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MEDICRIME COMMITTEE

Committee of the Parties to the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211)

1st Monitoring report:
The protection of public health through the MEDICRIME Convention in times of pandemics

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COMMITTEE

Committee of the Parties to
the Council of Europe Convention
on the counterfeiting of medical products
and similar crimes
involving
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1st implementation report
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through the MEDICRIME Convention
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Executive Summary

1. The 1st monitoring round of the implementation of the MEDICRIME Convention focuses on the **protection of public health through the MEDICRIME Convention in times of pandemics**. The report covers this theme in 13 of the 23 States which were Parties to the Convention at the time the monitoring round report was adopted.

2. The 1st report provides the general framework for the protection of public health in times of pandemics, addressing eight sets of issues: i) Prevention and Training; ii) Education; iii) Victims; iv) Cooperation and Information Exchange; v) Detection; vi) Investigation and Prosecution; vii) Sanctions and Aggravating circumstances; viii) Data collection

3. With regard to the need for prevention and training measures for those with responsibilities for combating counterfeit medical products, the MEDICRIME Committee found that the majority of Parties **have well-developed regulatory authorities that guarantee the quality, safety and efficacy of the medical products that they authorise for marketing**. Although the provision of training for health product regulators, police, and customs services is ongoing, it is not consistent in all these receiving the training and have experienced disruption during the COVID-19 pandemic. The MEDICRIME Committee regrets that the majority of Parties **did not recognise training for procurement programmes and the distribution of medical products as key areas for the effective of counterfeit medical products, especially during a pandemic**. **Review programmes on the effectiveness of training measures, the training of specialised investigation teams on counterfeit medical products with specialised investigation techniques, and the operation of awareness programmes on medical product waste management are largely non-existent**. The MEDICRIME Committee regrets that such deficiencies, in particular during pandemics, weaken the impact of other measures already in place by the Parties to combat counterfeit medical products and similar crimes involving threats to public health.

4. Regarding the identification of measures for the education of civil society on good practices to avoid procuring counterfeit medical products, the Committee found that the Parties provided the general public with information and conducted awareness-raising campaigns, in particular in avoiding procuring from unauthorised online sources and increasing awareness on counterfeit medical products related to the COVID-19 pandemic. Evidence was lacking regarding encouragement by the Parties of civil society to become engaged in delivering awareness-raising campaigns to the public, as was the extent of delivery by civil society of such campaigns. The Parties generally have legal provisions supporting the prohibition of the promotion, advertisement and dissemination of material relating to and the sale of counterfeit medical products, including by online means, generally, which includes during pandemics.

5. Related to the protection of victims the Committee found that **all the Parties have a system of protection for victims of criminal offences which can be applied to those victims arising from the counterfeiting of medical products and similar crimes**. It is relevant to highlight that the majority of the

Parties have adopted different measures to permit victim support and advocacy groups, NGOs and other groups to assist and support victims. Particularly relevant at this stage are the different measures to enable victims to report offences and to receive protection and assistance in respect of offences established in accordance with MEDICRIME Convention. While a majority of the Parties have adopted such measures, no Party has oversight arrangements to assess their effectiveness.

6. As regards the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate the effective investigation of counterfeit medical products and similar crimes, the Committee noted that **most Parties have systems in place that cover this purpose, even though some were general and not specific to counterfeit medical products**. However, **it is unclear** in the majority of the Parties **the extent to which these activities are supported by enabling legislation regarding counterfeit medical products and similar crimes**. The majority of Parties **do not have a review mechanism to check the effectiveness of these mechanisms**. The designation of a lead authority for cooperation and information exchange remains fluid, depending on the situation. While this may not pose a difficulty for some Parties, there is no review mechanism on the effectiveness of the decision-making on how the lead authority in this respect is made. The Parties have national contact points for information exchange and is supported by legislation on the transfer and receipt of evidence between countries, though it is noted that there is little evidence of the existence of Memorandums of Understanding and Data Sharing agreements either internally between authorities, or internationally with equivalent authorities. The MEDICRIME Committee stresses the **importance of designating contact points**, for both national and international contacts, and **supporting them by enabling information sharing and data exchange, including with civil society, industry, and service providers, as appropriate**.

7. As regards the various measures that may proactively be taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients, **the Committee regrets that the majority of the Parties have systems that were assessed as inadequate for this purpose**. The majority of Parties do not have mandatory or even adequate measures in place for the industry to report counterfeit medical products, notwithstanding that industry is expected in most Parties to proactively make such reports. While the majority of Parties have market sampling programmes for medical products, most of them were focused on regulatory quality defects and mostly on medicinal products only and were not specifically focused on counterfeit medical products. Few Parties included the sampling of medical products in public procurement programmes, and none in private procurement programmes. The Committee noted that a minority of Parties have legislation that enables customs services to detect, detain and act on counterfeit medical products using legislation in line with the Convention and without having to rely upon or be subordinate to intellectual property rights legislation. The **Committee regrets that none of the measures taken by the Parties to proactively detect counterfeit medical products relates to specific additional measures during a pandemic**. The Committee stresses the need to proactively detect instances of counterfeit medical products at all times, in particular during pandemics, and to close any

gaps in the detection system that may allow medical products supply to escape regulatory scrutiny.

8. As regards investigations and prosecutions, the first issue related to this section is to ascertain the correspondence between the domestic laws of the Parties and the definitions of certain concepts included in the MEDICRIME Convention, as well as with the offences set up in Articles 5 to 8 of the MEDICRIME Convention and with the liability of legal persons (Article 11, MEDICRIME Convention). At this point, the Committee noted that **the majority of the Parties have fully implemented at the internal level the definitions of Article 4, the main offences established in Articles 5 to 8, and the liability of legal persons connected with those crimes**. Nevertheless, a minority of Parties have implemented Article 8. b which remains an aspect that needs to be considered. Related to the existence of specialized national investigation services responsible for conducting criminal investigations in the field of counterfeiting of medical products and similar crimes, such specialization is still pending in some of the Parties. One key aspect in the field of investigation and prosecution is the existence of processes used to decide which investigative department is responsible for investigations in general. The Committee noted that all the Parties have either procedural rules or formal criteria in order to decide which investigative service or body is responsible or takes the lead for investigations when they arise. Nevertheless, certain Parties deal with complaints about counterfeiting of medical products and similar crimes involving threats to public health on a case-by-case basis by individual investigative services and bodies while other Parties collate complaints about those offences at a national level. Finally, it is also positive to confirm that in the majority of Parties all prescribed offences in Articles 5-8 and 9 are investigated and not subject to a complaint being made and maintained.

9. As regards sanctions and aggravating circumstances the MEDICRIME Committee noted that all the Parties have internal laws which permit the seizure, confiscation and disposal, including the destruction of medical products and other materials and instrumentalities employed to the commission of the offences established in Articles 5-8, MEDICRIME Convention. Related to the implementation at the internal level of the aggravating circumstances established in Article 13 MEDICRIME Convention, **the majority of the Parties fulfil the obligations established in Article 13**. As regards policies by the Parties for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s) (such as the trafficking of controlled substances in the same consignment as the counterfeit medical products), it was not possible to make an assessment on this in the majority of the Parties. Finally, a relevant measure consists of the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article 13. c). At this point, it is important to highlight that certain Parties have legal provisions to remove the professional status of both natural and legal persons.

10. **As to data collection**, the MEDICRIME Committee found that **this was not a high priority by the Parties**. In the majority of Parties, the data on counterfeit medical products and similar crimes is not collected during or related to

pandemics, or at all, except by a minority of Parties. No specific data collection system is evident in the majority of Parties and focal points are not tasked to collect such data. Some promising practices are evident in one Party that collects data on medical products during the COVID-19 pandemic. The collection of relevant data is necessary for a better understanding of the impacts of counterfeit medical products, on determining the true level of this type of crime, and in order to better support policy development and systems to protect public health through effective investigation and prosecution of offenders. **The designation of focal points tasked with collecting and assessing such data and making the data and analysis available is an urgent need**. The collection of data during times of pandemic, as well as more generally, is required to track the rapid changes in the profile of counterfeit medical products, in particular, those related to the treatment of conditions related to the pandemic.

11. The main recommendations by the MEDICRIME Committee on steps to improve or reinforce the protection of public health through the MEDICRIME Convention in times of pandemics in the areas covered by this report are provided at the end of the Introduction. Specific recommendations are at the end of each chapter. All chapters also highlight a number of promising practices. Cooperation between all relevant stakeholders, and civil society, is essential to ensure that effective measures against the counterfeiting of medical products and similar crimes involving threats to public health are enacted and implemented.

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INTRODUCTION

- The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter "the MEDICRIME Convention", or "the Convention") provides that a specific monitoring mechanism be set up to ensure effective implementation of its provisions by Parties (Article 25§1 and Rule 25).

- This report is the 1st implementation report developed by the Committee of the Parties to the MEDICRIME Convention (hereinafter "the Committee"). It contains the Committee's evaluation of the implementation by Parties of a selected number of provisions of the MEDICRIME Convention which are relevant to assess the situation in Parties with respect to "the protection of public health through the MEDICRIME Convention in times of pandemics".

Thematic monitoring

- During its 3rd meeting[1], the MEDICRIME Committee decided that its monitoring work (i.e. the assessment of the implementation of the Convention) would be based on a thematic approach.

- As available data show that offences involving medical products committed during a pandemic target critical funding through fraudulent scams, counterfeiting of vital protective personal equipment and critical medical devices to save lives and to detect the presence of the disease, and attacks on critical infrastructure in the fight against the disease, the MEDICRIME Committee decided that the first monitoring round would focus on "The protection of public health through the MEDICRIME Convention in times of pandemics".

- On 27 May 2021, the MEDICRIME Committee adopted this thematic questionnaire. Its purpose is to collect specific information on how Parties implement the MEDICRIME Convention with respect to offences involving medical products and similar crimes involving threats to public health and related to a pandemic. The replies to the questionnaire are assessed against the related background information provided by the Parties when answering the "General Overview" questionnaire on the implementation of the MEDICRIME Convention (hereinafter "Country Profile Questionnaire" or "CPQ") and any other relevant information from reliable sources.

Rule 26 of the Committee of the Parties' Rules of Procedure:

"(…) 2. The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".

3. Parties shall co-ordinate with their respective domestic authorities to collect replies, which shall be submitted to the secretariat in one of the official languages of the Council of Europe within the time limit set by the MEDICRIME Committee. The replies to the questionnaires shall be detailed, as comprehensive as possible, answer all questions and contain all relevant reference texts. The replies shall be made public, unless a Party makes a reasoned request to the MEDICRIME Committee to keep its reply confidential.

[1] Committee of the Parties of the MEDICRIME Convention, List of decisions, 3rd Plenary meeting (1-3 December 2020), T-MEDICRIME-(2020) LD, paragraph 4.5

4. The MEDICRIME Committee may also receive information on the implementation of the Convention from non-governmental organisations and civil society involved in preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health, in one of the official languages of the Council of Europe and within the time limit set by the MEDICRIME Committee. The secretariat transmits these comments to the Party or Parties concerned.
5. The secretariat may request additional information if it appears that the replies are not exhaustive or are unclear. Where warranted, with the consent of the Party or Parties concerned and within the limits of budgetary appropriations, the bureau may decide to carry out an on-site visit to the Party or Parties concerned to clarify the situation. The bureau shall establish guidance as to the procedure governing the on-site visits."

Parties involved in the 1st monitoring round

- The 1st monitoring round concerns the following 13 Parties which ratified the Convention: **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland and Türkiye.** 23 countries had ratified the Convention at the time that the MEDICRIME Committee adopted the thematic report to the 1st monitoring round[2]. Five countries ratified the Conventions since the adoption of the questionnaire on 27 May 2021[3]. The thematic questionnaire was circulated to th countries.

- The above 13 Parties were monitored within a timeframe to create momentum around specific aspects of the monitoring theme. The remaining Parties who did not respond to the questionnaire were not monitored for the purpose of this report (**Albania, Belarus, Benin, Burkina Faso, Cote d'Ivoire, Guinea, Moldova, Niger, Slovenia, and Ukraine)[4].** This report, therefore, does not address the situation in each country separately. It presents an overview of the trends which emerge from the comparison of the situation in all Parties.

- Article 25§1 of the MEDICRIME Convention provides that the "Rules of Procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention using a multisectoral and multidisciplinary approach". Accordingly, Rule 25 §3 and Rule 26§2 provide that:

> ***"Rule 25§3*** *The monitoring round shall be initiated by addressing a questionnaire on the implementation of the relevant provisions of the Convention with respect to the selected theme. The Parties shall respond to the questionnaire within the time limit set by the MEDICRIME Committee.*
> *"**Rule 26§2*** *The secretariat shall address such questionnaires to the Parties through the member in the MEDICRIME Committee representing the Party to be monitored and who will act as "contact point".*

[2] See Appendix I for the State of signatures and ratifications and Appendix III for the State of play of replies to the Questionnaire.

[3] Cyprus on 05 September 2023; Morocco on 19 April 2022; Niger on 10 March 2022; Slovenia on 01 September 2022; Côte d'Ivoire on 01 November 2023

[4] It is noted that, in accordance with Rule 25§3, all Parties to the Convention have a requirement to respond to the 1st monitoring round questionnaire within the timeframe decided by the MEDICRIME Committee.

The Committee appreciates that all the information submitted by Parties was made public and underlines that the replies to the questionnaire were its main source of information to prepare this report.[5]

Structure of the Report

- The provisions of the MEDICRIME Convention have been grouped under different sections in this report without automatically following the structure of the Convention. This methodological choice in no way intends to prioritise the various provisions of the Convention: equal importance is attached to all rights and principles therein.

- This report does not seek to collect information on the general legislative and institutional framework established by Parties to implement the Convention. It focuses only on specific legislative and other measures taken or envisaged to protect public health from counterfeiting of medical products and similar crimes in the context of pandemics.

- For the purpose of this report, the notion of a pandemic will include the COVID-19 pandemic as well as other major health crises declared by the World Health Organisation as pandemics, epidemics or public health emergencies of international concern (PHEIC), including the Zika virus epidemic in 2015, the Ebola pandemic in 2014, the Middle East Respiratory Syndrome (MERS) in 2012, the H1N1 Influenza pandemic in 2009, the H5N1 outbreak in 2005, and the severe acute respiratory syndrome (SARS) in 2003.

- The Parties were requested to respond to all questions marked **mandatory** as they are essential to the monitoring round. It was also requested, where possible, that all questions marked **optional** could be answered. There were 18 questions marked as mandatory and 22 questions marked as optional.

- This report has eight main chapters

  - The first chapter collects information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics.
  - The second chapter identifies measures aimed at educating civil society on good practices in avoiding the risk associated with counterfeit medical products
  - The third chapter identifies measures focused on the protection of victims' rights.
  - The fourth chapter focuses on the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation
  - The fifth chapter is an appreciation of the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients.
  - The sixth chapter concerns the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic.

[5] All replies to the questionnaire are online at Appendix IV

- The seventh chapter identifies specific legislative and other measures that have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating to offences committed in a pandemic.
- Finally, the 8th and last chapter concerns the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Each chapter
  - Provides a comparative overview of the situation in the eight Parties monitored, whilst a country-specific summary of the information is appended to the report in the form of tables[6]
  - Highlights promising practices where identified to effectively implement the Convention
  - Identifies the shortcomings and recommends steps that the Parties should take to improve or reinforce the protection of public health in times of pandemics, using the Convention

- Finally, in its recommendations to Parties, the MEDICRIME Committee decided to use the terms to "urge", "consider" and "invite" to mark different levels of urgency as follows:

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  - "**Urge**": when the MEDICRIME Committee assesses that legislation or policies are not in compliance with the Convention, or when it finds that despite the existence of legal provisions and other measures, the implementation of a key obligation of the Convention is lacking;
  - "**Consider":** when the MEDICRIME Committee agrees that further improvements are necessary for law or in practice to fully comply with the Convention;
  - "**Invite**": when the MEDICRIME Committee believes Parties are on the right track but it wishes to point at one or several promising practices to reinforce the implementation of the Convention

[6] See Appendix IV

I. PREVENTION AND TRAINING

This part aims to collect information on policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics. The questions concern all those whose responsibilities it is to procure and supply medical products, and those who encounter them or their impact on public health having regard to pandemics.

This part concerns:

- training and awareness programmes aimed at those people in particular, as well as the public in general.
- prevention measures aimed at raising awareness of the availability of counterfeit medical products.

The intention of the Convention is to promote putting in place measures to prevent circumstances whereby counterfeit medical products can infiltrate the supply chain. This means that there need to be regulatory regimes to ensure the quality and safety of medical products from the initial stage of procurement of excipients and active substances, both regarding medicinal products, accessories, and parts and materials, both regarding medical devices (Art 18.1). The regulatory regime extends to the manufacturing process of medical products, excipients and active substances, parts and materials, and accessories (Art 18.1) through to the distribution to the market. The Explanatory Report noted that the terms *supplying and offering to supply* (in Article 4 - Definitions, and Article 6- Substantive Criminal Law Offences) are not specifically defined in the Convention but are understood to cover acts of *procuring*. While not specifically mentioned in the Convention, the regulatory regime necessarily includes procurement programmes, both public and private. Therefore, the procurement and distribution of medical products are recognised by the Convention as a key area for prevention (Art 18.2)

The intention of the Convention is that all activities that result in criminal activities involving threats to public health are considered. To this end, it involves not only the legal supply chain but supplies conducted outside that chain and evades the regulatory supervised chain (Article 18. 3.c). In addition, it intends that Parties take measures to develop arrangements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products and similar crimes.
This part of the report focuses on the legislative, policy, and other measures taken by Parties to provide effective preventive measures and train healthcare professionals, providers, police and customs authorities and relevant regulatory authorities.

This part of the report considers prevention and training matters in the context of times of pandemics. This is of particular concern having regard to the global experience

during the COVID-19 pandemic and the expectation that both pandemics and epidemics will continue in times to come[7].

Article 18 – Preventive measures

1. Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.
2. Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products.
3. With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, inter alia, for:
    a. training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;
    c. the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories

Explanatory Report

113. Paragraphs 1 and 2 of this article provide for two key preventive measures in combating counterfeiting of medical products and similar crimes, namely the introduction, at the national level, of quality and safety requirements of medical products on the one hand, and measures ensuring the safe distribution of such products on the other. The ad hoc committee considered that it should be left to the domestic law of each Party to define the appropriate quality and safety requirements as well as the measures ensuring safe distribution. One example of the latter type of measure, which a Party may consider adopting, the introduction of adequate track and trace systems on medical products could be mentioned. Such track and trace systems can have different features but are essentially ensuring the traceability of a given medical product to its source.

114. As further preventive measures, paragraph 3 requires Parties to provide:

a. training of health care professionals, providers, police, customs and relevant regulatory authorities in order to better prevent and combat the counterfeiting of medical products and similar crimes;

c. to supervise all professional activities within the distribution chain of medical products, as well as to develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

115. The actions enumerated in paragraphs 1 - 3 are not to be considered as an exhaustive list.

[7] Imagining the future of pandemics and epidemics: a 2022 perspective. Geneva: World Health Organization; 2022.

61. As in the case of Article 6 above, the terms "supplying" and "offering to supply" are not specifically defined, but understood to cover, in the widest sense, the acts of procuring, selling or offering for free as well as brokering and promoting (including through advertising these products.

1.1. Prevention and Training

1.1.1. Measures to provide training to those in the distribution, wholesale and procurement programmes (Article 18.2)

- While considering the specific wording chosen by domestic legislation to implement Article 18, this should appreciate the intention of the Convention that measures are put in place to ensure that prevention and training are effective and not limited to actions enumerated in Article 18 and that these actions are not considered to be an exhaustive list.

- The Convention does not intend that prevention and training matters be provided and implemented by the Criminal Law alone, or at all. Matters of *quality* and *safety* are scientific standards that are more appropriately dealt with by regulatory laws, as is the case of all the Parties in this report (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye**).

- Matters of the *distribution* of medical products are, likewise, dealt with by regulatory laws, whilst provisions for training are often not regulated by law but are provided through strategic planning and other measures, such as structured training sessions, awareness-raising programmes, and round table discussions (**Armenia, Belgium, Croatia, Hungary, Morocco, Portugal, Spain, Switzerland, and Türkiye**). Reliance is also placed on the distributors and wholesalers to train their own staff on preventive measures, including measures mandated by Good Wholesale and Distribution Practice Guides (GDP) (**Belgium, France, Spain**).

- None of the parties, except one (**the Russian Federation)** (and that was not specific to counterfeit medical products alone), reported the structured involvement of procurement programmes in training regimes to prevent the counterfeiting of medical products. This may indicate that there are no measures by the Parties, whether legislative, policy, strategic or other arrangements to either specifically or generally train those in either public or private procurement programmes on the prevention of counterfeiting and similar crimes involving medical products involving threats to public health.

- None of the parties had introduced specific measures for training the distribution sector to combat counterfeit medical products and similar crimes having regard to the impact of a pandemic other than considering their health safety measures of holding training and conferencing events virtually. Specific measures in this context of a pandemic are intended to mean having and implementing preventive

and training measures to take into account the impact of a pandemic on the procurement and distribution of medical products. Such impacts may involve resource challenges due to the diversion of finance and staff to critical pandemic response areas and the absence of staff due to illness and temporary redeployment, all of which leave deficiencies in trained staff in the prevention of counterfeit medical products being procured and distributed in the market, including through procurement programmes.

- It is important, in this context, that Parties are prepared through having and implementing legislative, policy, strategic and other measures to provide training in critical procurement and distribution areas with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources and priorities are under stress.

Promising Practices

- In Hungary, the National Board Against Counterfeiting (NABC), working under Decree 287/2010, created the Action Plan Against Counterfeiting and has a Working Group on actions against the counterfeiting of medical products. The Action Plan fosters cooperation between the relevant bodies/authorities in organising common training, consultations and the production of information documentation. One such booklet, specifically for customs on identifying falsified vaccines and medical products, was produced by the health product regulator, the National Institute of Pharmacy and Nutrition (OGYÉI), NBAC and pharmaceutical wholesalers.

- In the **Russian Federation**, the Academy of Management of the Ministry of the Interior conducts annual professional development programmes for the improvement of managers in procurement

Recommendations

- Urges **Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Russian Federation, and Spain** to ensure that policies, strategies and measures are provided for the training of those involved in public and private procurement programmes for medical products.

- Urges **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye** to develop contingency plans, strategies and other measures to provide training in critical procurement and distribution areas of medical products with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources and priorities are under stress, including during pandemics.

1.1.2. Measures to provide training to healthcare practitioners, police, customs, and health product regulators (Article 18.3.a)

- The Convention does not specify the measures to be taken to provide training. This is left to national authorities to decide within their capacities and structures how training to prevent counterfeiting of medical products and similar crimes should be conducted and the frequency that such training should be provided to healthcare practitioners, police, customs, and health product regulators.

- Training, including online seminars and workshops, involving police, customs, regulatory authorities, and healthcare professionals appear to be ongoing, and with some disruption during the COVID-19 pandemic, in a number of the Parties (**Armenia** (partial), **Belgium, Bosnia and Herzegovina, France, Morocco, Portugal, Spain, Switzerland, and Türkiye).** The training is not uniformly delivered among relevant authorities, with some consistently providing training (**France, Spain**) while others focus mainly on Customs training (**Switzerland)**, or regulatory authorities training only (**Armenia**) or regulatory authorities and healthcare professionals (Croatia)**.** The judiciary and public prosecutors are specifically trained in one Party (**Spain).** Others have strategic plans to conduct training of police and other authorities during the period to 2025 (**Bosnia and Herzegovina and Croatia).** One Party **(Hungary)** has a Working Group on counterfeit medical products, as part of the National Board against counterfeiting, and it coordinates plans among authorities on training in this area. One Party **(Türkiye)** provides training in the area as an adjunct with training of Customs on IPR infringements.

- None of the parties, except three (**France, Portugal, Spain**), consistently provide training to the police, customs, regulatory authority and healthcare practitioners. This results in a fragmented training provision and is not in keeping with the requirements or the spirit of Article 18. 3.a. of the Convention. It does not provide training to all of those who need it on an ongoing basis. This weakens the protections for public health intended by the Convention.

- It is recommended that Parties introduce as a standing item in their policies, strategic plans and arrangements for training on a multi-authority and multi-disciplined basis to include police, customs and regulatory authorities, at a minimum, as well as healthcare practitioners and legal professionals, to appreciate the risks arising with the procurement and distribution of counterfeit medical products and similar crimes. This training should be systematic and ongoing among those mentioned in the Convention as needing the training.

Promising practice

- In **Portugal**, two laws were introduced mandating training of police, customs, and health product regulators on the handling of medical products acquired during COVID-19. A set of crimes against health were identified for the Judicial Police to prioritise actions for prevention and investigation during this period. This highlighted anticipated crimes to be committed during COVID-19 and provided training and guidance notes that included anticipated frauds, embezzlement, abuse of trust, corruption, abuse of power, and undue advantage.

- In **Spain**, The Ministry of Justice includes judges, magistrates, public prosecutors, and selected police officials in training and awareness-raising on the problems and risks posed by counterfeit medical products. The Spanish Judicial School of the General Council of the Judiciary, in collaboration with the Council of Europe (HELP programme and the European Committee on Criminal Matters), has launched the 'MEDICRIME' course to expand the capabilities and skills of judges to improve the national implementation of the MEDICRIME Convention.

Recommendations

- Urges **Armenia, Croatia, Cyprus, Hungary, and the Russian Federation** to develop policies, strategies and other measures to provide training to healthcare practitioners, police, customs and regulatory authorities, to each of the sectors, and not just to some of them, on the prevention of counterfeit medical products, active substances, accessories, parts and materials. This should consider cross-training between the relevant authorities to ensure completeness and sustainability.

- Invites **Armenia, Belgium, Cyprus, Bosnia and Herzegovina, Switzerland and Türkiye to** provide training on a consistent basis, particularly in times of pandemic, to each of the sectors for healthcare practitioners, police, customs and regulatory authorities, and not just to some of them. This should consider cross-training between the relevant authorities to ensure completeness and sustainability.

- Invites **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Hungary, Portugal, Russian Federation, Switzerland** and **Türkiye** to introduce as a standing item in their policies, strategic plans and arrangements for the training of police, customs and regulatory authorities, as well as healthcare practitioners and legal professionals, to appreciate the risks arising with the procurement and distribution of counterfeit medical products and similar crimes to ensure the sustainability of the training.

1.1.3. Measures to provide training to specialised investigation units/bodies in specialised techniques (including financial investigation) (Article 16(2)

Article 16.2 – Criminal Investigations

Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Explanatory Report

107. The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.

108. Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national law. The notion of "principles of national law" should be understood as also encompassing basic human rights, including those provided under Article 6 of the European Convention on Human Rights (ECHR).

109. "Effective investigation" is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording "where appropriate", Parties are not legally obliged to apply any or all of these investigative techniques, but if a Party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.

110. The ad hoc committee underlined that "controlled delivery" is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products and similar crimes. The measure of "controlled delivery" is already foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances and the Second 16 Additional Protocol to the European Convention on Mutual Legal Assistance in Criminal Matters (ETS No. 182).

- Article 16, Paragraph 2, provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national laws. This requires taking into account basic human rights in accordance with Article 6 of the ECHR. That intends to include the application of the principle of proportionality, as referred to in the Preamble of the Convention, where such specialised techniques are applied.

- The Explanatory Report explains that the Convention does not require a Party to use specialised techniques in the investigation of crimes involving counterfeit medical products and similar crimes, and where they do, it must be appropriate

in the circumstances. The type of specialised techniques mentioned in Article 16.2 includes electronic and other forms of surveillance as well as infiltration operations, and controlled deliveries. This is not an exhaustive list and it is open to domestic law to determine which, if any, and the circumstances in which such specialised techniques may be used in relation to the investigation of offences provided by the Convention. The Explanatory Report emphasises that controlled delivery is one of the most important investigative tools available to authorities in the area of investigating the counterfeiting of medical products and similar crimes.

- This part of the report considers the legislative, policy, and other measures taken by Parties to provide effective measures to train specialist investigation bodies that focus on counterfeit medical products and similar crimes with specialist techniques, as mentioned above.

- While it is likely that most Parties have law enforcement specialist units/bodies responsible for the application and training in specialist techniques, as described above, the provision of measures for training in specialist techniques to specialist investigation units in the investigation of counterfeit medical products and similar crimes has been noted to be largely absent, except in two Parties (**France, Spain**). In the absence of a national policy not to implement such techniques relating to the investigation of counterfeit medical products, then the intention of the MEDICRIME Convention has not been met.

Recommendations

- Invites **Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Hungary, Morocco, Portugal, Russian Federation, Switzerland, and Türkiye** to consider reviewing their legislation, plans, strategic and other measures to provide training in specialist investigative techniques to specialist units/bodies in the investigation of counterfeit medical products and related crimes, where appropriate.

1.2. Oversight programmes to assess the frequency and effectiveness of training provided (Article 18.1, 2 and 3. a)

- The success and effectiveness of any training are judged by its outputs and outcomes. This can often be challenging to assess other than the taking place of training events and the completion by the relevant officials of the training programme. This part seeks to determine the extent to which the Parties have conducted oversight programmes to assess the frequency and effectiveness of the training provided, as required by Article 18. 1, 2, and 3.a. of the Convention.

- This part also seeks to determine the extent to which revision programmes have been put in place to ensure that remedial actions are addressed by training on any deficiencies observed regarding existing training programmes required by Article 18.1, 2, and 3. a.

- Training programmes conducted in some Parties are assessed for competence and knowledge following the completion of the training programme (**France, Russian Federation**). In one case (**France**) the training is followed in due course by retraining to ensure continued competence by officials. While training validation is a necessary component of training provided, this is considered a different step and process to oversight programmes to assess the effectiveness of the training having regard to the value delivered by officials in the conduct of their duties following the training.

- Two Parties (**Croatia, Hungary**) plans to begin assessment programmes one year after training officials. One Party (**Armenia**) relies on its regulatory quality management system to ensure any remedial actions needed are identified and completed.

- In none of the Parties is it evident that there is an oversight programme to assess the frequency and effectiveness of training already provided. This is, at best, left to retraining programmes (one case only). The frequency of training is not addressed by the Parties, except in one case (**France**) due to its programme of mandatory retraining.

Recommendations

- Urges all parties to the MEDICRIME Convention to train all of the relevant sectors involved in combating the counterfeiting of medical products and similar crimes. This should be followed up by an oversight programme to assess the effectiveness of the training provided.

1.3. Awareness-raising and training programmes for those involved in procurement programmes, wholesalers, distributors, and entities responsible for cleaning and waste disposal on the disposal of medical product waste (Article 18. 1, 2 and 3)

- Waste management and care in the disposal of medical products are crucial elements in the prevention of counterfeit medical products and used or disposed of legitimate medical products being illegally diverted back onto the legitimate supply chain or on unregulated markets.

- While waste management was not specifically enumerated in the Convention or mentioned in the Explanatory report, the Explanatory report emphasised that actions enumerated in paragraphs 1-3 of Article 18 are not to be considered as an exhaustive list. In this context, the Parties are expected to go beyond the wording and give full effect to the spirit and intent of the Convention. While reliance may be placed on domestic environmental laws to satisfy the issues raised in this part of the report, it should be emphasised that the Convention is concerned with the protection of and minimising the risk to public health and compliance with criminal law. This is an added emphasis for all connected to

cleaning and waste disposal of medical products beyond compliance with environmental regulations for environmental purposes.

- Further actions to prevent the recycling of waste and disposed of medical products, whether they are counterfeit or legitimate in nature, are required as part of the end-to-end management of the medical products in the procurement and distribution systems, and in healthcare facilities that consume the medical products and create medical product waste.

- It is expected that seized counterfeit medical products, and the instrumentalities associated with their production and fraudulent diversion would be destroyed by order of a court or otherwise in accordance with domestic laws. They should not be sold or otherwise supplied for any use other than the taking of samples for tests, examinations or analyses undertaken in support of efforts to prevent crime and protect public health. Some seized ancillary equipment associated with medical devices may have alternative uses and may be disposed of by the health product regulator when authorised by the Court while ensuring that there will be no diversion to facilitate further counterfeiting of medical products.

- Within the legal supply chain and in healthcare facilities, large quantities of legitimate medical product waste are produced. This is where the Convention expects end-to-end management of medical product waste control and that everyone connected with waste management of medical products is aware of their responsibilities and the associated health risks and criminal law consequences with deviating from these. Where this is not the case, such loopholes need to be eliminated by approved processes and audited to ensure compliance. For this to happen, a provision for awareness-raising and training programmes for cleaning and disposal staff, and those who manage them, is required. As for other programmes, this should be assured by ongoing oversight to assess the effectiveness and frequency of the awareness-raising.

- Specific awareness-raising programmes for cleaning and waste management of medical products are not conducted as a general measure by any of the Parties. Instead, a more focused application of regulatory licensing requirements is applied to the distribution and wholesale trade in medical products. A similar focus is applied to the retail pharmacy trade (**Croatia**, **France**) where all staff are required to train on the proper disposal of medical product waste to prevent illegal recycling.

- Only one country (**France**) had awareness-raising arrangements for police investigators that focus on medical product-related crime. One Party (Croatia) has established cooperation between police, customs and other regulatory authorities in medical waste management, including in cases of seized counterfeit medical products. It is unclear if the cooperation arrangements are supported by structured awareness-raising programmes or training provided for this purpose. One Party reported that it did not have an awareness-raising campaign for police (**Hungary**) and another (**Croatia**) reported that it did not have such a campaign for cleaning staff or recycling staff, but plans for training

and written instructions to be prepared for this. While one Party (**Portugal**) has a law for the integrated waste management system for the collection of packaging, medical products and medical devices, this is not focused on the prevention of recycling of falsified medical products. One Party (**Croatia**) has a law on the management and disposal of waste medical products, which, while it is not designed specifically to prevent the recycling of counterfeit or disposed of medical products, can contribute to such prevention. It is unclear if the law is supported by structured awareness-raising programmes or training provided for this purpose. One Party (**Türkiye**) requires disposal at certified waste centres to ensure that such products cannot be reused or recycled. This is supported by law and by information to authorities and organisations that no product removed from the supply chain can be used. This presumes that the same regime applies to medical products removed from the illicit supply chain for disposal at certified waste centres. However, there are no structured awareness-raising or training programmes provided for this purpose.

- A greater emphasis was given to awareness-raising in the proper disposal of medical waste during COVID-19 (**Belgium, Portugal, Russian Federation, Spain, Switzerland**). Specific instructions or laws were provided concerning the handling of labelling materials for disposal in Belgium, while a focus was also placed on securing both medical products for disposal in special containers and/or in separate rooms (**Belgium, Croatia, Russian Federation, Spain, Switzerland**). In Belgium, weekly briefings were held for officials in charge of vaccination centres and those responsible for vaccine waste disposal in connection with the potential for fraud with vaccine waste, including associated labelling. In the Russian Federation, regular updating took place of healthcare officials and medical institutions on the turnover and disposal of medical waste, including personal protective equipment. It also updated its instructions on the destruction of seized counterfeit and substandard medicines and drafted similar instructions for medical devices (awaiting adoption). In Spain, special instructions were issued relating to medical waste associated with COVID-19 in domestic dwellings, hospitals, ambulances, health centres and laboratories. In Switzerland, a reference to the MEDICRIME Convention was provided to vaccination centres and supervising authorities regarding waste in the context of the COVID-19 pandemic. It is understood, in all cases, that the reference to medical waste included waste associated with medical products and not just non-medical product medical waste. Greater emphasis on medical product waste could heighten awareness of this aspect of all medical waste.

- The use of authorised waste management entities under specific contracts was in place (**Belgium, Croatia, Portugal, and Türkiye**) for the disposal of waste medical products. It is anticipated, but not specifically noted by other Parties, that such waste disposal arrangements are put in place in many of the Parties and done so for environmental law purposes.

- No Party engaged in awareness-raising campaigns for those involved in the procurement of medical products. This is a clear gap in the protection of public health and creates risks that may remain undetected in breach of criminal law.

- No Party undertook reviews of the effectiveness of the governance and supervision of medical products waste disposal programmes. No party undertook any awareness-raising programmes on the importance of proper disposal and risks associated with disposed of medical product when illegally diverted for re-use.

Promising Practices

- In **Belgium**, during the COVID-19 pandemic, special instructions were issued to public vaccination centres regarding the disposal of waste materials, including vials, labelling, stickers and packaging. Waste labels were required to be made illegible. All waste was required to be put into special containers and stored in a secured area. Every week, videoconferences were held for all vaccination centres during which potential fraud with medical product waste and best practices concerning waste disposal were discussed.

- In **Spain**, during the COVID-19 pandemic, all sectors, including the public, that had the possibility to create and dispose of waste medical products had their awareness raised through instructions to minimise the risk to human health and to comply with all legal requirements, not just environmental requirements, relating to medical waste and COVID-19 pandemic.

Recommendations

- Urge Parties to undertake awareness-raising campaigns for those engaged in the procurement of medical products to close this gap in protecting public health.

- Urges Parties to ensure that arrangements are put in place for all relevant sectors, including those mentioned in Article 18.1, 2, and 3 of the Convention, that handle medical product waste to be included in awareness-raising campaigns.

- Invites Parties to build on their response to the COVID-19 pandemic challenges regarding cleaning and waste disposal and to apply equivalent and enhanced actions in non-pandemic times.

- Invites Parties to ensure that their awareness-raising campaigns on the management and disposal of waste medical products highlight medical product waste and the consequence of illegal diversion associated with public health risks and the consequences flowing from the Criminal Law relating to the illegal diversion of medical products.

- Invites Parties who have not provided information of their national situation, to examine their situation in the light of the foregoing considerations, and urges

them, where appropriate, to bring it into line with the requirements of the Convention.

1.4. Reviews of the effectiveness of the governance and supervision of medical product waste disposal (Article 18.1, 2, 3.c)

- Considering the emphasis placed on waste management and disposal of medical product waste during the COVID-19 pandemic by some Parties, it would be expected that an assessment of the effectiveness of the outcome of those measures, including governance and supervision measures associated with them, would have been undertaken on an ongoing or periodic basis. Only one Party (**Croatia**) was considered to have conducted such assessments as a routine regulatory activity. This was assessed as not having been conducted by any other Party.

- One Party (**Belgium**) could be assessed as having conducted an informal review on a weekly basis through conferences to discuss the measures put in place and best practices on disposal and fraud risks with the public vaccination programme. In addition, physical visits to the vaccination centres were carried out to ensure that any changes to the method of work found necessary were reported on and put in place. However, this is not a formalised effectiveness review of the governance and supervision of medical waste disposal and it is assessed as being restricted to the vaccination programme and not to all medical product waste.

- As there were no reviews of the effectiveness of the governance and supervision of medical product waste disposal, there were no awareness-raising programmes conducted by the Parties on the importance of disposal programmes and the risks that can arise from inadequate governance and supervision.

Recommendations

- Urge the Parties that have not yet achieved this stage to put in place measures to conduct reviews of the effectiveness of the governance and supervision of medical product waste to follow on from the conduct of awareness-raising and training measures on medical waste disposal.

- Urge all Parties to include effectiveness reviews on governance and supervision to the widest possible extent, not only including procurement entities and authorities but also including healthcare facilities that create medical product waste.

1.5. Specific preventive actions targeted at specific medical products involved in a recent pandemic and the results achieved (and not already mentioned above) (Article 18.1, 2, 3)

- One Party (**Hungary**) put measures in place for the police and the *Operational Group for the Protection against the Coronavirus Pandemic*, a Government body, regularly conducted awareness raising among the public about the risks associated with counterfeit vaccines and counterfeit PCR tests. One Party (**Morocco**) implemented special control measures through the Direction Génerale de la Sûreté Nationale related to counterfeit medical products during COVID-19 pandemic. One Party (**Croatia**) implemented new rules, including the requirement for Customs authorities to check whether an importer had an authorisation from the medicinal product and medical device regulatory authority (HALMED), while another rule specifically involved measures to identify importations of COVID-19 vaccines. No Party provided information on any results from the special measures adopted on any specific medical products during any recent pandemic.

II. EDUCATION

This section seeks to identify measures aimed at educating the public and on good practices in avoiding the risks associated with counterfeit medical products.

At this point, MEDICRIME Convention refers specifically to the implementation of awareness-raising campaigns oriented to the public in general in the field of counterfeit medical products and similar crimes.

Article 18 – Preventive measures

(…)

3. With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, *inter alia*, for:

(…)

b. the promotion of awareness-raising campaigns addressed to the general public providinginformation about counterfeit medical products;

EXPLANATORY REPORT

Article 18 – Preventive measures

114. As further preventive measures, paragraph 3 requires Parties to provide training of health care professionals, providers, police, customs and relevant regulatory authorities in order to better prevent and combat the counterfeiting of medical products and similar crimes; to promote awareness-raising campaigns with the involvement of relevant non-governmental organisations and the media; to supervise all professional activities within the distribution chain of medical products, as well as to develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

115. The actions enumerated in paragraphs 1 - 3 are not to be considered an exhaustive list.

2.1 Strategies, policies and other measures planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, in particular, those that may be encountered during a pandemic

This part seeks to determine the strategies, policies and other measures that have been planned or implemented, with a view to educating the public on risks associated with counterfeit medical products, especially those that may be encountered during a pandemic in connection with what is established by Article 18.3.b. In particular, it is intended to obtain information on such education policies related to the following aspects:

i. on purchasing conducts of medical products, including through real-world/physical and virtual means, such as online and e-commerce platforms and social media;
ii. on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems;
iii. on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes.

Almost all the Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye**) have implemented measures with a view to educating the public on risks associated with counterfeit medical products, on purchasing conducts of medical products, including through real-worlds/physical and virtual means, such as online and e-commerce platforms and social media.

- Policies on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within each Party's authorised supply systems are also generally adopted by the different Parties. One Party (**Türkiye**) has specific awareness-raising activities for this purpose.

- Most Parties have adopted strategies for developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes. Only two Parties (**Armenia**, and **Cyprus**) report not having specific programmes in this area.

- It has also to be mentioned that the majority of the Parties **(Croatia, France, Hungary, Morocco, Russian Federation, Spain,** and **Switzerland)** have strengthened those measures, policies and strategies during the COVID-19 pandemic or have implemented specific awareness-raising programmes focused on the counterfeiting of medical products in the context of the pandemic.

- Except for Croatia, no other Party has issued a report on the results of these measures.

Promising Practices

- **Croatia,** includes a report on the results of the measures taken under this point. According to the analysis made by Croatia, systematic media monitoring shows that a significant number of articles about counterfeit medical products and the threat of buying medicines on the internet are published in print publications, as well as on news portals, based on the information the Agency for Medicinal Products and Medical Devices (HALMED) provides. Likewise, national TV and radio stations regularly include reports on the dangers of counterfeit medical products in collaboration with the Agency.

- In **France,** in the context of the crisis, various communications have been sent to the general public by the authorities concerning the risks associated with counterfeit medical products. For example, the National Agency for the Safety of Medicines and Health Products has published on its website:
  - Safety information, opinions and recommendations on medicines in the face of COVID-19,
  - information for buyers, distributors and importers on the qualification of products used during the COVID-19 health crisis,
  - a warning against products presented on the Internet as solutions to COVID-19, including Artemisia annua.
  - In its anti-counterfeiting plan for 2021-2022, the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) focuses on counterfeit medicines and medical devices in times of health crisis.

- **Portugal**, while not specific to a pandemic situation, has online educational campaigns and warning campaigns on buying medical products online.

- In **Switzerland,** Swissmedic provides a variety of targeted information (factsheets, etc.), primarily on its website (www.swissmedic.ch). Regarding the current pandemic, Swissmedic has issued specific warnings:
  - against purchasing non-conforming and illegal medical devices,
  - against purchasing illegal medicinal products which are used against COVID19, and
  - against purchasing COVID-19 vaccines on a private basis.

  Swissmedic regularly conducts public awareness campaigns (e.g. annual Operation PANGEA, and awareness campaigns within the framework of the Swiss public-private partnership STOP PIRACY), and issues regular publications regarding the health risks of purchasing drugs from illegal sources and *ad hoc* publications regarding specific dangerous illegal medicines.

- One Party (**Türkiye**) has specific awareness-raising activities for this purpose. and to use medical practitioner-prescribed medicines and counselling

services by healthcare professionals. In this context, the Ministry of Health provides advice on Rational Drug Use on social media.

Recommendation

- **URGES Belgium, Bosnia and Herzegovina, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, and Türkiye** to issue reports on the measures, policies and strategies taken to the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products.

- Urges **Armenia** and **Cyprus** to develop strategies, policies and other measures with a view to educating the public on risks associated with counterfeit medical products in the context of purchasing conducts including through real-world/physical and virtual means, promoting good purchasing conduct among the public to encourage rational use of medical products and the avoiding procurement from sources that are not within the Party's authorised supply chain, and on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes

2.2. Policies to encourage or support the involvement of civil society in promoting measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context.

- This concerns policies by the Parties that encourage or support civil society to become involved in measures to combat, prevent, detect and respond to counterfeit medical products. This was focused on a pandemic period, but also more generally outside of a pandemic. Examples of civil society provided included industries, publishers and academia and include all relevant groups and non-governmental organisations impacted by counterfeit medical products and similar crimes.

- This part was not intended to focus on the actions by authorities in conducting education, training or awareness-raising measures, either to the industry or directly to the public. It is assessed that all the Parties focus on training the industry and raising public awareness among the industry and the public rather than encouraging or supporting civil society to promote such measures to prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context.

- Two Parties (**Russian Federation, Spain**) may indirectly have such policies. It is not clear if civil society is encouraging awareness-raising to the public as part of public policy or self-driven (**Spain**). For example, Spanish Associations of the Pharmaceutical Industry issued precautions to be taken when purchasing medical products during the COVID-19 pandemic. It is unclear if this has been a result of State policy to encourage the Associations to raise this awareness during the pandemic or an industry initiative. In the Russian Federation, there is

a scheme to recognise civil society, mainly the public, who actively participate in measures to combat, prevent, detect and respond to counterfeit medical products, including during a pandemic. It is not clear if this results from the promotion of a State policy to encourage civil society to make this recognition or if it is a direct State recognition.

Recommendation

- Urges Parties to review their legislation, policies and measures on the promotion of clear supports to encourage the involvement of civil society in conducting awareness-raising activities on combating, preventing, detecting and responding to counterfeit medical products during a pandemic, or in a more general context.

2.3. Active engagement by civil society in raising public awareness of the risks arising from counterfeit medical products (Article 18.3.b)

- The focus of this part is to ascertain whether and to what extent that civil society is engaged in awareness-raising directed to the general public providing information about the risks associated with the consumption of counterfeit medical products.

- None of the Parties, except one Party **(Türkiye)** point to the active engagement by civil society in raising public awareness. This does not mean that such engagement does not take place, only that it is not being recorded by public authorities as part of awareness-raising campaigns addressing the general public on risks associated with the procurement and consumption of counterfeit medical products.

- In one case **(Türkiye)** pharmacy unions and chambers carry out awareness-raising activities to the general public, as well as to healthcare professionals.

- Three Parties (**Croatia, Hungary, Russian Federation**) point to engagements that have the possibility of civil society being involved in awareness raising among the public, though this remains unclear. In Croatia, the brand owners conduct awareness-raising campaigns on counterfeit products more generally but this may also have the possibility of increasing the public's consciousness of the risks arising with counterfeit medical products. In Hungary, the National Board against Counterfeiting (NBAC) engages with civil society, among others, in awareness raising on counterfeit products, including counterfeit medical products. This has the possibility for civil society groups to subsequently become involved in awareness-raising to their respective interest groups or more generally to the public on the risks of procuring and consuming counterfeit medical products. In the Russian Federation, the authentication app available to the public on smartphones requires some promotion for its use and has the possibility of civil society groups being involved in this awareness-raising among

the public to detect and respond to counterfeit medical products. It remains unclear the extent to which civil society is actually involved in such awareness-raising or whether this remains within the domain of the State.

Recommendations

- Urges all Parties to review their legislation, policies and measures on data collection to record instances of the provision by civil society to the general public on awareness-raising campaigns and programmes on the risks arising from procuring and consuming counterfeit medical products.

- Invite all Parties to share with civil society the opportunity to be involved in conducting awareness-raising to the general public on the risks arising from counterfeit medical products.

2.4. Legislative provisions, strategies, plans and preventive measures taken to prevent the promotion, advertisement and dissemination of material, where they are contrary to internal laws, during a pandemic and generally

- The majority of the Parties **(Armenia, Belgium, Croatia, Cyprus, France, Russian Federation, Portugal, Spain, Switzerland,** and **Türkiye)** have legal provisions to prohibit the promotion and selling of falsified medical products.

- Other strategies, plans and preventive measures have been taken by different Parties to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product, offers, when they are contrary to internal laws, during a pandemic and generally. One Party (**Morocco**) has two specialised bodies within the Brigade Nationale de la Police Judiciaire dealing with these matters. While the two bodies are mainly focused on crimes associated with new technologies, it is unclear to what extent these also act to prevent the promotion, advertisement and dissemination of material, when they are contrary to internal laws, where new technologies are not involved.

PROMISING PRACTICES:

- In **Spain,** Resolution of 26 March 2021 of the State Secretariat for Health published the Agreement with the Association for Self-Care of Health and the Association for the Self-Regulation of Commercial Communication on Advertising Medicinal Products for Human Use addressed to the public (BOE of 7 April 2021). The purpose of the Convention is to establish the most appropriate mechanisms for the assessment of advertisements addressed to the public concerning medicinal products for human use, in order to ensure that they are produced with the necessary truth, clarity and objectivity and that all the conditions imposed by the relevant legislation are fulfilled. In this regard, the Association for the Self-Care of Health (ANEFP) undertakes to review all draft advertising messages submitted to them on a voluntary basis by pharmaceutical bodies to advertise medicinal products for human use to the public through a Technical Committee for the review of this type of advertising and to inform pharmaceutical bodies of all the incidents noted in the review of the advertising projects submitted and studied. In turn, the Association for the Self-Regulation of Commercial Communication (AUTOCONTROL) undertakes to examine through its Technical Cabinet, and in accordance with its procedures, advertising campaigns sent by ANEFP under the 'ANEFP stamp' and those sent to it on a voluntary basis by advertisers, agencies or media in relation to advertising messages on medicinal products for human use addressed to the public.

- In **Switzerland,** Swissmedic is the central contact point for reports regarding illegal advertisements and illegal offers and takes measures against any such activities contrary to national laws. Together with the national communications authority, Swissmedic has assessed all new websites that included "COVID", "corona" or similar words in their domain name in order to uncover illegal offers or activities. Furthermore, Swissmedic conducts specifically targeted monitoring of illegal virtual information and offers. In order to optimise such monitoring, tools for automated monitoring of illegal medicinal products and non-conforming medical devices are currently being evaluated.

Recommendation

- Urges **Bosnia and Herzegovina** to implement legislative provisions, strategies, plans and preventive measures to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8. a, and 18. 3. b).

III. VICTIMS

This section aims at identifying measures focused on the protection of victim rights.

In particular, the purpose of this section is to ensure the protection of the rights and interests of victims of counterfeiting of medical products and similar crimes by recognising, by means of legislative and other measures, a set of rights established in Article 19 MEDICRIME Convention. (Those rights relate mainly to access to information relevant to their case and which is necessary for the protection of their health, assistance to victims in their recovery, and the right to compensation from the perpetrators).

This part also aims to ensure the standing of the victims at all stages of criminal investigations and proceedings. Of particular relevance is the protection of some rights and interests of the victims at this stage; i.e., to be informed of their rights and the services at their disposal, right to be heard, to provide them with appropriate support services, measures for their safety, etc.

Article 19 – Protection of victims

Each Party shall take the necessary legislative and other measures to protect the rights andinterests of victims, in particular by:

a ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;

b assisting victims in their physical, psychological and social recovery;

c providing, in its domestic law, for the right of victims to compensation from the perpetrators.

Article 20 – The standing of victims in criminal investigations and proceedings

1 Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:

a informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;

b enabling them, in a manner consistent with the procedural rules of domestic law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;

c providing them with appropriate support services so that their rights and interests are duly presented and taken into account;

d providing effective measures for their safety, as well as that of their families andwitnesses on their behalf, from intimidation and retaliation.

2 Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.

3 Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.

4 Each Party shall take the necessary legislative and other measures to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their State of residence.

5 Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its domestic law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

Explanatory Report

116. The protection of, and assistance to, victims of crime has long been a priority in the work of the Council of Europe.
117. The horizontal legal instrument in this field is the European Convention on the Compensation of Victims of Violent Crime (ETS No. 116) from 1983, which has since been supplemented by a series of recommendations, notably Recommendation No. R (85) 11 on the position of the victim in the framework of criminal law and procedure, Recommendation No. R (87) 21 on the assistance to victims and the prevention of victimisation and Recommendation Rec (2006)8 on assistance to crime victims.
118. Furthermore, the situation of victims has also been addressed in a number of specialised conventions, including the Council of Europe Convention on the Prevention of Terrorism (CETS No. 196), the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197), both from 2005, and the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS No. 201) from 2007.
119. Taking into account the potential grave consequences for victims of counterfeiting of medical products and similar crimes, the ad hoc committee found that it was justified to provide specifically for the protection of such victims, and also to ensure that victims of the crimes established under this Convention are being kept informed about relevant developments in their cases by the competent national authorities and that – subject to the domestic law of the Parties – they are being given the possibility to be heard and to supply evidence.
120. It is recalled that, the term "victim" as defined in Article 4, letter k, of the Convention is limited to natural persons suffering adverse physical or psychological effects as a result of one or more of the conducts criminalised by the Convention. Legal persons are not intended to be covered by the provisions on victims in Chapter VI, nor are persons suffering only financial losses in connection with a conduct criminalised under the Convention.

Article 19 – Protection of victims
121. Article 19 provides for the protection of the rights and interests of victims, in particular by requiring Parties to ensure that victims are given access to information relevant for their case and necessary to protect their health; that victims are assisted in their physical, psychological and social recovery, and that victims are provided with the right to compensation under the internal law of the Parties. As regards the right to compensation, the ad hoc committee noted that in a number of member states of the Council of Europe, national victim funds are already in existence. However, this provision does not oblige Parties to establish such funds.

Article 20 - The standing of victims in criminal investigations and proceedings
122. This article contains a non-exhaustive list of procedures designed to victims of crimes established under this Convention during investigations and proceedings.

These general measures of protection apply at all stages of the criminal proceedings, both during the investigations (whether they are carried out by a police service or a judicial authority) and during criminal trial proceedings.

123. First of all, the article sets out the right of victims to be informed of developments in the investigations and proceedings in which they are involved. In this respect, the provision provides that victims should be informed of their rights and of the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the charges, the general progress of the investigations or proceedings, and their role as well as the outcome of their cases. As indicated by the wording "the general progress of the investigation or proceedings", Parties are not always obliged to provide victims with detailed information about aspects of the investigation or the proceedings, as in some situations the proper handling of the case may be adversely affected by the disclosure of information.

124. The article goes on to list a number of procedural rules designed to implement the general principles set out in Article 20: the possibility, for victims, of being heard, of supplying evidence (subject to this being permitted under the domestic law of a Party), choosing the means of having their views, needs and concerns presented, directly or through an intermediary, and of being protected against any risk of retaliation.

125. Paragraph 2 also covers administrative proceedings, since procedures for compensatingvictims are of this type in some states. More generally, there are also situations in which protective measures, even in the context of criminal proceedings, may be delegated to the administrative authorities.

126. Paragraph 3 provides for access, free of charge, where warranted, to legal aid for victimsof counterfeiting of medical products or similar crimes. Judicial and administrative procedures are often highly complex and victims therefore need the assistance of legal counsel to be ableto assert their rights satisfactorily. This provision does not afford victims an automatic right to free legal aid. The conditions under which such aid is granted must be determined by each Party to the Convention when the victim is entitled to be a party to the criminal proceedings.

127. In addition to Article 20 paragraph 3, dealing with the status of victims as parties to criminal proceedings, the States Parties must take account of Article 6 of the ECHR. Even though Article 6, paragraph 3.c. of the ECHR provides for the free assistance of an officially assigned defence counsel only in the case of persons charged with criminal offences, the case law of the European Court of Human Rights (Airey v. Ireland judgement, 9 October 1979) also, in certain circumstances, recognises the right to free assistance from an officially assigned defence counsel in civil proceedings, under Article 6, paragraph 1 ECHR, which is interpreted as enshrining the right of access to a court for the purposes of obtaining a decision concerning civil rights and obligations (Golder v. United Kingdom judgment, 21 February 1975). The Court took the view that effective access to a court might necessitate the free assistance of a lawyer. For instance, the Court considered that it was necessary to ascertain whether it would be effective for the person in question to appear in court without the assistance of counsel, i.e. whether he could argue his case adequately and satisfactorily. To this end, the Court took account of the complexity of the proceedings and the passions involved – which might be incompatible with the degree of objectivity needed in order to pleadin court – so as to determine whether the person in question was in a position to argue his own case effectively and held that, if not, he should be able to obtain free assistance from an officially assigned defence counsel. Thus, even in the absence of legislation affording access to an officially assigned defence counsel in civil cases, it is up to the court to assess whether, in the interests of justice, a destitute party unable to afford a lawyer's fees must be provided with legal assistance.

128. Paragraph 4 is based on Article 11, paragraphs 2 and 3, of the Framework Decision of 15 March 2001 of the Council of the European Union on the standing of victims in criminal proceedings. It is designed to make it easier for victims to file a complaint by enabling them tolodge it with the competent authorities of the state of residence. A similar provision is also found in Article 38, paragraph 2 of the Council of Europe Convention on the Protection of Children against Sexual

Exploitation and Sexual Abuse (CETS No. 201) of 25 October 2007.
129. Paragraph 5 provides for the possibility for various organisations to support victims. The reference to conditions provided for by internal law highlights the fact that it is up to the Parties to make provision for assistance or support, but that they are free to do so in accordance with the rules laid down in their national systems, for example by requiring certification or approval of the organisations, foundations, associations and other bodies concerned.

3.1. Measures for the protection of victims

This part of the report focuses on the existing national laws and policies for the protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic due to the increased risks arising. Additionally, and in case of the absence of such laws and policies, it is intended to ascertain what steps are being planned, if any, for the setting of such policy or in the absence of which, for victims of crime relating to counterfeit medical products generally.

- All the Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**) have a system of protection for victims of criminal offences which can be applied to those victims arising from the counterfeiting of medical products and similar crimes.

- This system of protection of victims emerges either from the Criminal Procedure Code or from a specific Act devoted to the protection of victims of criminal proceedings, depending on the legislative model adopted at this point by each Party. In general, the protection of victims of crime relating to counterfeit medical products includes rights such as the right to protection from intimidation and retaliation, the right to be heard without undue delay after the filing of a criminal report, the right to be informed, etc.

- Most Parties **(Armenia, Belgium, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have established services for the support of victims of criminal offences which are generally at the disposal of victims arising from the counterfeiting of medical products and similar crimes.

- There does not appear to be a focus, except for one Party **(Belgium)** on the introduction of specific measures for the protection of victims of counterfeit medical products and similar crimes having regard to the impact of a pandemic.

Promising Practices

- In the case of **Belgium**, several initiatives can be mentioned.

- The Federal Police Central Directorate for Serious and Organised Crime (DJSOC), section *'i2-IRU'* (Internet Investigation) performs daily checks on open sources (Internet) looking for websites offering counterfeit and/or non-mainstream products. Every file is communicated to the competent partner services (the services of the integrated police, Customs, the Federal Agency for Medicines and Health Products (FAMHP) and/or the Federal Public Service (FPS) Economy, in relation to detected violations and/or the type of product offered.

- The Board of Public Prosecutors has designated the *'i2-IRU'* service as the central point of contact for investigations (COL NR. 10/2020 of 2nd of April 2020 concerning CORONAVIRUS – Guidelines of the College of Prosecutors General on the fight against fake web shops and fake news sites):
  - online stores that sell counterfeit medicines or products related to Covid-19;
  - fake online stores that offer genuine/fake items in the same setting;
  - fake news sites (mainly or exclusively related to Covid-19) that can explicitly endanger public health. This illustrates the collaboration between all the competent authorities to tackle these websites.
  - -The FOD Economie has also developed a webpage containing all the information for victims (preventive measures such as how to recognize these websites), what to do when a person becomes a victim and includes a referral button to a central reporting point where the victim can report the facts. The website also refers to a film available on *Youtube* that explains this in a comprehensive and intelligible way.

Recommendation

- Urges **Bosnia and Herzegovina** to proceed to define the term "victim" in criminal and procedural laws (Criminal Code and Code of Criminal Procedure) in accordance with international standards. At present, victims are treated through the terms "injured party" and "witness". This legislative process has already begun at the internal level, taking into account the provisions relating to the protection of victims in accordance with the MEDICRIME Convention.

3.2. Measures to protect the rights of victims at all stages of the criminal proceedings

This part aims to ascertain the measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4).

- Six Parties **(Bosnia and Herzegovina (**with the limitation that it has not yet defined the term *victim* in its legislation**) Belgium, Croatia, France, Hungary, and Portugal)** highlighted the existence of legal provisions at the internal level that comply with the obligations established at Article 20, MEDICRIME Convention in order to protect the rights of victims at all stages of the criminal proceedings.

- One Party (**Russian Federation**) highlighted the existence of security measures at the internal level oriented to the protection of the victim, witness or other participants in criminal proceedings, as well as their relatives and partners (art. 20.1.d. MEDICRIME Convention).

- Three Parties (**Armenia, Cyprus, Morocco**) provided information on the protection of victims' rights during the criminal proceedings but did not specify if all the rights established in Article 20.1 to 4 MEDICRIME Convention were covered.

- Three Parties (**Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

- No Party provided information on the implementation at the internal level of Article 20.4, MEDICRIME Convention.

3.3. Assistance and support to victims by victim support and advocacy groups, NGOs, etc.

This part seeks to ascertain what measures are provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceedings and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health. It is intended to obtain information on any such organisations and groups/bodies and on any assessment of the effectiveness of such involvement by such providers (Article 20.5).

- Six Parties **(Belgium, Croatia, Hungary, France, Morocco, Russian Federation)** adopted different measures to permit victim support and advocacy groups, NGOs and other groups to assist and support victims.

- Seven Parties (**Armenia, Bosnia and Herzegovina, Cyprus, Portugal, Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

Promising Practices

- In **Belgium,** victim support is implemented by the victim support services, recognized and/or subsidized by the Communities, and independent of the police and judicial authorities. The general mission of these services is to

provide social and psychological assistance to victims of crime and their relatives. These services provide free social support aimed at restoring the living conditions of the victim and reintegration into work life or psychological support adapted to the needs of the victims in order to help them find a new life balance. This support can be short or long-term depending on the needs of the victim. The interviews are organized according to the needs and the mobility of the victims: they can be organized in a room that offers guaranteed discretion or, if necessary, in the victim's home or another place (e.g. a hospital) and even via phone. When the victim wishes so, they can be accompanied by a representative/employee of the service when taking certain steps (e.g. doctor's visit, or a visit to a police station). When needed, the victim is referred to more specialized organizations (e.g. for psychotherapeutic support).

- In **Croatia**, the Ministry of Justice and Public Administration RoC has the *Service for Victim and Witness Support*, the central body for coordination of the development of the victim and witness support systems. At court level, *Victim and Witness Support Departments* at the courts exist. The National Committee delivered the National Strategy for Victim and Witness Support 2016-2020 and the Action Plan.

- In **France**, victim support associations approved by the Ministry of Justice offer victims of counterfeit medical products and similar crimes and their relatives, free of charge and in complete confidentiality, guidance, information and assistance in their legal, administrative and social procedures. As part of their missions, these associations, composed of lawyers, psychologists, social workers, provide victims with moral and psychological support to avoid the risk of secondary and repeated victimization. This comprehensive and multidisciplinary care, which is free of charge, is a long-term provision. The offer of services is thus arranged at regular stages and adapted to the victim. Assistance may be provided before any legal proceedings, during the judicial proceedings and beyond them. Where necessary, approved victim support associations provide appropriate referrals to specialized services, such as social and medical-psychological services. This assistance benefits any victim regardless of their nationality and place of residence, including even if they reside abroad.

- In **Hungary**, the regional victim support services, the *Victim Support Centres and the Victim Support Line* provide information and assistance tailored to the individual needs to victims of all crimes. Victim support services cooperate and maintain contact with state bodies, non-governmental organizations and religious communities. As a result of this cooperation, in case a victim support service is unable to provide direct assistance through its services or that a victim needs a kind of service that can better be provided by another organization, the service directs the victim concerned to governmental or non-governmental organizations as well as to religious communities best suited to providing personalized, fast and efficient assistance. For this reason, the

Ministry of Justice has concluded numerous cooperation agreements with organisations.

3.4. Support to victims by civil society

This part seeks to ascertain whether civil society is actively engaged in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b).

- Two Parties **(Croatia, Hungary)** have civil society actively engaged in providing supportive facilities for redress and recovery for victims of crime generally. These are not specific to medical product-related crimes, but to all victims of crime.

- Eleven Parties (**Armenia, Belgium, Bosnia and Herzegovina, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**) did not provide any relevant information on this matter, having the possibility to do so as the question was optional.

PROMISING PRACTICES:

- In **Croatia**, the Network of Support and Co-operation for Victims and Witnesses of Criminal Offences is a network of 10 civil society organizations with 1 coordinator, that is created with the intent of providing assistance and support for victims and witnesses of criminal offences in 17 Counties in Croatia. Network members participated in numerous education and thematic lectures with the aim of improving knowledge and strengthening their capacity to provide support and assistance to victims and witnesses. All members of the Network are continuously participating in educational activities with the aim of providing the highest quality services to victims and witnesses. Coordinator of the Network, Women's Room and member organization, Victim and Witness Support Service are members of Victim Support Europe, a leading European umbrella organization advocating on behalf of all victims of crime, no matter what the crime, no matter who the victim is.

- In **Hungary** the White Ring Public Benefit Association operates alongside the government victim protection system, providing assistance not only to victim of the counterfeiting of medical products and similar crimes.

3.5. Measures to enable victims to report offences. Protection and assistance to victims

This part seeks to determine what measures are in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention and whether there is any oversight to assess the effectiveness of such measures.

- Five Parties **(Belgium, Croatia, France, Hungary, Russian Federation)** have put in place different measures to enable victims to report offences and to receive protection and assistance in respect of offences established in accordance with MEDICRIME Convention.

- No Party has oversight arrangements to assess the effectiveness of such measures.

- Two Parties (**Spain, Switzerland**) did not provide any relevant information on this matter, having the possibility to do so as the question was optional.

Promising practices

- In **Croatia**, the Ministry of Justice and Administration has a leading role in the institutionalization of the victim and witness support system within the judicial system and coordinates the victim and witness support system in the Republic of Croatia. Among other measures in place, it is worth highlighting the *National Call Center*, which provides a free service and informs victims of their rights and ways of their realization, emotional support, and refers victims to other institutions and organizations that can provide them with professional assistance. The *National Call Center for Victims of Crime and Misdemeanors 116 006* is available for the entire territory of the Republic of Croatia every working day from 08:00 to 20:00.

- In **Hungary**, the *Victim Support Line* (06 80 225 225), which is available free of charge 24 hours a day, is run by the Ministry of Justice to ensure that citizens who are victims can obtain information outside office hours. By calling the Victim Support Line, victims can obtain legal information and advice on their rights and obligations in criminal proceedings, the types of assistance available, the conditions and procedures for applying for assistance, and the best way to solve the problem they are facing.

Recommendation

- Invites the Parties to establish oversight to assess the effectiveness of the measures in place to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention.

IV. COOPERATION AND INFORMATION EXCHANGE

This section focuses on the ability of authorities/services to cooperate and exchange information in order to facilitate the conduct of effective investigations and the importance of such cooperation and exchanges.

- This part aims to promote the co-operation and information exchange between

the competent authorities in order to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health.

- Co-operation between public authorities and the commercial and industrial sectors in this field is also a key aspect so as to tackle the counterfeiting of medical products and similar crimes involving threats to public health.

- Although Article 17 MEDICRIME Convention does not oblige Parties to establish new bodies tasked with co-ordination, due to the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes there is a need to strengthen the existing frameworks for co-operation.

- The MEDICRIME Convention requires that there be adequate training of the persons, units or services in charge of co-operation and information exchange.

Article 17 – National measures of co-operation and information exchange

1 Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.

2 Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

Explanatory Report
Article 17 – National measures of co-operation and information exchange
111. Networking at national level based on a multidisciplinary and multisectoral approach is a key element in the fight against counterfeiting of medical products and similar crimes. Hence, Article 17 provides for the co-operation and information exchange between the competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health. In this context, it should be noted that the involvement of health authorities in the prevention and combat of counterfeiting of medical

products and similar crimes is a key tool for the efficient protection of public health. In addition, paragraph 2 provides for the facilitation of assistance to be provided by the relevant commercial and industrial sectors to the competent authorities as regards risk management, as these sectors have vast product expertise.

112. The ad hoc committee found that the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes, from law enforcement to health,usually requires a strengthening of the existing frameworks for co-operation. In particular, the Council of Europe model on a network of Single Points of Contact (SPOC) developed by the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED) of the Council of Europe served as inspiration for the drafters of the Convention. This Council of Europe SPOC model is already in operation within the EU medicines enforcement sector and has been tabled as a working contact model for the International Medical Product Anti-Counterfeiting Task Force (IMPACT) under the World Health Organization (WHO), by the Permanent Forum on International Pharmaceutical Crime and the International Criminal Police Organization (INTERPOL). However, Article 17 does not in any way oblige Parties to introduce new bodies tasked with co-ordination and information exchange in the field of counterfeiting of medical products and similar crimes.

4.1. Information on national strategies or action plans on cooperation and exchange of information between authorities to combat the counterfeiting of medical products and similar crimes

This part seeks to ascertain whether the Parties has or plan to make a national strategy and/or action plan on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar offences and if these instruments specifically address pandemic situations (Article 17.1).

- Formal systems of exchange of information between public authorities (health authority, customs administration, police) have been established in most of the Parties **(Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Portugal, Russian Federation, Spain,** and **Switzerland).**

- In some Parties, systems (mostly informal, i.e. not based on a legal provision or formally institutionalized) of exchange of information with the private sector (pharmaceutical wholesalers and manufacturers) are already in place **(France, Hungary).**

- No national strategy and/or action plan on cooperation and exchange of information between authorities/services to combat counterfeiting of medical products and similar offences has specifically addressed pandemic situations, except in one Party (**Portugal**).

- Five Parties (**France, Hungary, Portugal, Russian Federation, Switzerland**) established some arrangements in this field in light of the context of a pandemic (COVID-19).

- No other Party has adapted existing systems to take account of the impact of a pandemic.

Promising practices

- In **France**, in terms of public health, all French authorities in charge of these issues have initiated exchanges of information by collaborating directly (ANSM, ANSES (ANMV), National Order of Pharmacists, Orders of Physicians, BNEVP, DIRRECTE, DGCCRF, AFLD, CNAMTS, etc.). Since the outbreak of the pandemic, OCLAESP (Office Central de Lutte Contre les Atteintes à l'Environnement et à la Santé Publique) has largely anticipated the various threats likely to arise from this situation, particularly in view of foreseeable shortages, or drugs presented as remedies or vaccines marketed. This action has prevented or ended many initiatives by criminal organizations seeking to take advantage of this pandemic situation.

- In **Hungary**, cooperation has become more frequent, not only between the public authorities (health, tax and customs administration, police) but also between the pharmaceutical wholesalers and manufacturers concerned. Cooperation is based on legal mandates and also includes informal contacts between the relevant authorities. Police set up an online anti-drugs and anti-counterfeiting task force with representatives of the relevant authorities. This working group will develop recommendations and methodological guidelines in this area.

- In Portugal, working groups were set up during the COVID-19 pandemic between police, Defence, and health authorities to deal with incidents of health-related crime.

- In the **Russian Federation**, the strategy of medicines supply to the population of the Russian Federation for the period up to 2025, approved by the order of the Ministry of Health of Russia, provides for the establishment of a system of effective cooperation of interested federal executive authorities, executive authorities of the constituent entities of the Russian Federation and public organizations to achieve coordinated actions in the implementation of the Strategy's activities. One of the prospects for the implementation of the Strategy is to significantly reduce the existing risks associated with the circulation of falsified and substandard products, as well as with adverse events of medicines for human use.

- In **Switzerland**, within the national network of authorities engaged in enforcement against counterfeit medical products and similar crimes, a scheme on cooperation and information exchange has been adopted at their annual MEDICRIME Meeting. This scheme is promoted, reviewed and adapted annually by the national network. This scheme is valid for non-pandemic and pandemic situations. Additionally, Fedpol (Federal Office of Police) has established a distribution list for all information related to COVID-19 that comes through police networks. The national contact point according to Article 22.2 is included in this distribution list.

Recommendation

- Urges **Cyprus, Morocco, and Türkiye** to continue developing legislative and other measures in order to fully implement MEDICRIME Convention in this field.

4.2. Formal support for the implementation of a national strategy/ action plan to facilitate effective investigation

4.2.1. National Strategy or formal action plan supported by legislation

This concerns the implementation of a national strategy and/or action plan and whether it is underpinned by enabling legislation for the transfer and receipt of information and data between authorities/bodies and to other jurisdictions (Articles 17.1, 17.3, 21.1, and 21.2) in order to facilitate effective investigations.

- As noted above, not all Parties have such a formal national strategy or action plan. In some cases (**Belgium, Switzerland**), it is unclear whether the structures and measures in place result from a formal national strategy or are ad hoc in nature, but recognising that they exist on a continuous basis. In some cases (**Armenia, Croatia, Russian Federation**), there is national legislation that enables cooperation and information sharing but it is unclear whether this follows from a national strategy or action plan, or a recognition of the need to underpin by laws cooperation and information exchange relating to counterfeit medical products and similar crimes. A number of Parties (**Bosnia and Herzegovina, France, Hungary, Morocco, Spain**) either did not have a national strategy that is supported by enabling legislation, notwithstanding that such cooperation and information takes place, or they did not respond on this issue, having the possibility to do so as the question was optional.

- Three Parties (**Cyprus, Portugal, Türkiye**) provided no response to this question, having the possibility to do so as the question was optional.

4.2.2. Memorandums of Understanding and Data Sharing Agreements

Some Parties (**Bosnia and Herzegovina, Croatia, Hungary, Russian Federation**) have in place agreements between authorities/bodies at the national level involving the health authority, Ministries, police and customs administration. It is unclear if these are formal or informal arrangements, except in one Party (**Croatia**) which has a formal Memorandum of Understanding between the regulator (HALMED) and the Ministry of Internal Affairs. In one Party (**Morocco**), informal arrangements exist between law enforcement, including the Customs service, and the Ministry of Health to provide information relating to counterfeit medical products coming to attention from intelligence and investigations activities. In other cases (**Hungary, France**) the agreements relate to crime in general but are not specific to counterfeit medical products and similar crimes and may not include the health authorities. Some Parties

have not indicated whether such agreements are in place (**Armenia, Belgium, Spain, Switzerland**).

- Cooperation and information sharing arrangements at the international level specific to counterfeit medical products and similar crimes are not always clear on whether this is supported by a Memorandum of Understanding or that data can be shared in accordance with a Data Sharing or similar agreement. It is clear that the Parties participate in such activities, for example, from their participation in the INTERPOL-coordinated Operation Pangea on combating falsified medical products trafficking and supply, in particular through the use of online platforms. One Party (**Russian Federation**) has Memorandums of Understanding with countries outside of the MEDICRIME Convention on matters related to the quality, safety and efficacy of medical products and which include counterfeit medical products. It is unclear whether this focus is only on health product-related regulatory matters of product quality or whether it also includes criminal matters relating to the investigation of counterfeit medical products and similar crimes.

- Most Parties (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Russian Federation, Spain, Switzerland**) did not illustrate practical measures that ensure the implementation and effectiveness of any Memorandum or Data Sharing Agreement to facilitate effective investigations. One Party (Morocco) actively disseminates information between relevant authorities and services on counterfeit medical products arising from intelligence and investigative activities. One Party (**Russian Federation**) outlined that it reports offending online platforms to the Federal body responsible for online communications and mass media.

- Three Parties (**Cyprus, Portugal, Türkiye**) provided no response to this, having the possibility to do so as the question was optional.

- The use of Memorandums of Understanding and Data Sharing agreements by the Parties, that are specific to or specifically include as part of a wider agreement matters relating to combating counterfeit medical products and similar crimes, is deficient. The support of enabling legislation for national strategies or action plans appears wanting in most of the Parties. No reviews are conducted by the Parties on the effectiveness of measures in the area of cooperation and information exchange to facilitate effective investigations. These deficiencies leave weaknesses in the existence and/or effectiveness of cooperation and information exchange between the authorities/bodies at national and international levels.

Recommendations

- Urges all Parties to put in place a formal national strategy or action plan to enable cooperation and information exchange to facilitate effective investigation to

combat counterfeit medical products and similar crimes involving threats to public health.

- Urges all Parties to have a clear legislative scheme to support a national strategy or action plan to enable cooperation and information exchange to facilitate effective investigation to combat counterfeit medical products and similar crimes involving threats to public health.

- Urges the Parties to make use of Memorandums of Understanding and Data Sharing Agreements to the fullest extent among the relevant national authorities, and where appropriate with equivalent bodies in other countries and with relevant international organizations in combating counterfeit medical products and similar crimes.

- Urges the Parties to conduct periodic reviews on the effectiveness of measures to support cooperation and information exchange in order to facilitate effective investigation.

4.3. Designated lead and participation in the cooperation arrangements among authorities/bodies

- The requirement for the participation of authorities from health, customs, police and other competent authorities in the exchange of information and cooperation in accordance with domestic law in order to facilitate effective investigation is evident from the Convention (Article 17.1, 17.2). For this to be effective, the designation of a lead authority, the participating operational authorities and the lead overview and review authority need to be clear to all authorities.

- Only two Parties (**Croatia, Russian Federation**) have indicated lead responsibilities for authorities, with police and customs services taking the lead depending on the situation and with the health product regulator in both cases being responsible for providing product information, and analysis of suspect medical products. One Party (**Belgium**) has flexible arrangements to assign the lead authority and participating authorities depending on the issue arising. None of the Parties was clear on the circumstances of how the decision on the lead authority may be decided in any case. No Party conducted oversight or review on the effectiveness of arrangements in this regard.

- Nine Parties (**Bosnia and Herzegovina, Cyprus, France, Hungary, Morocco, Portugal, Spain, Switzerland, Türkiye**) did not provide any information on this matter, having the possibility to do so as the question was optional.

Recommendation

- Urges all Parties, where not already achieved, to implement clear measures in relation to cooperation and information exchange to decide on which authority takes the lead and how participation in operational plans is decided.

4.4. Cooperation and information-sharing arrangements involving civil society, industry and service providers.

- The focus of cooperation and information-sharing arrangements involving civil society, industry and service providers in order to facilitate effective investigation is foreseen by the Convention (Article 17.2 and 17.3.a).

- Given the wide range of private sector and non-governmental organizations that may become involved with counterfeit medical products and may interact with authorities in the prevention, detection and investigation of counterfeit medical products and similar crimes, those mentioned by the Convention (Article 17.3.a) should be seen as indicative and not finite. For example, service providers may include financial and money transfer services, and e-commerce, while logistic providers may include postal and delivery services, and others.

- No Party has established such arrangements with all of the relevant private industry, service providers, civil society and social media platforms.

- Five Parties (**Belgium, Croatia, France, Russian Federation, Türkiye**) have varying cooperation and information-sharing agreements involving either private industry and associations, and logistics. Only Belgium's health product regulator (FAMHP) includes elements of all these, including postal and delivery services, and social media platforms. France's law enforcement on falsified medical products and similar crimes (OCLAESP) has an arrangement with the industry G5 group involving eight industry laboratories that detect online platforms promoting counterfeit medical products. The health product regulators in Croatia, which appears to be a more general arrangement that is not focused on effective investigation, and the Russian Federation have arrangements with the industry and associations. Morocco cooperates with the Union of Internet Service Providers under the Law on the Regulation of Content on the Internet and Combating Crime Committed such content, and two other relevant laws, and with social media platforms on actions to remove content that is contrary to law.

- While not all the authorities in any of the Parties are involved in all of the arrangements with all of the industry, civil society and social media platforms, it may be sufficient for one authority to specialise in the arrangement so long as it provides the benefits of the arrangement to the other authorities.

Recommendations

- Urge the Parties to ensure, in order to facilitate the effective investigation of counterfeit medical products, that cooperation and information-sharing arrangement involve civil society, industry, service providers, e-commerce and social media platforms, at a minimum.

- Urge the Parties to ensure that the arrangements established by authorities benefit all of the authorities involved in the prevention, detection and investigation of counterfeit medical products and similar crimes.

- Urge the Parties to ensure that arrangements for cooperation and information-sharing to facilitate effective investigation are formalised and subject to periodic review for effectiveness.

4.5. Arrangements with and membership with investigative or advisory bodies/groups dedicated to combating counterfeit medical products and similar crimes

- The Explanatory Report (at 112) mentions a number of groups, as examples, that authorities involved in combating counterfeit medical products and similar crimes, including law enforcement and health authorities, usually engage in the strengthening of existing frameworks for cooperation. The focus may vary from regulatory to law enforcement investigation depending on the group. All have a significant focus on building cooperation and information exchange in their chosen area.

- A number of these types of networks involve some of the Parties as members: the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (**CD-P-PH/CMED**) of the Council of Europe[8] providing experts from national authorities (**Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Spain, Switzerland**); the World Health Organization's Member State Mechanism on Substandard and Falsified Medical Products (**MSMech SF)**[9] (**Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye**); Permanent Forum on International Pharmaceutical Crime **(PFIPC)** (**Belgium, France, Spain, Switzerland**); Working Group of Enforcement Officers of the EU Heads of Medicines Agencies **(HMA WGEO)**[10] (**Belgium, Croatia, Cyprus, France, Hungary, Portugal, Spain, Switzerland**), the International Criminal Police Organization **(INTERPOL) and EUROPOL**. All of these networks, except for INTERPOL and Europol, are dedicated to combating counterfeit medical products and similar crimes and are mostly advisory and supportive of their members in the areas of cooperation and information sharing. Both INTERPOL and EUROPOL have dedicated groups to focus on counterfeit medical products and similar crimes, but the organisations have overall remits beyond counterfeit medical products and are dedicated to crime in general.

- The groups mentioned are indicative only and other dedicated groups exist regionally and internationally. Parties may also be involved with healthcare, industry and other associations that have overall remits beyond counterfeit medical products.

[8] While Armenia, Cyprus and Portugal provided no response to this topic, it is understood that the Parties provide delegates from their health authorities to attend meetings
[9] While Armenia, Cyprus, Morocco, Portugal and Türkiye provided to response on this topic, it is understood that the Parties provide delegates from their health authorities to these groups
[10] While Cyprus and Portugal provided no response on this topic, it is understood that the Parties provide delegates from their health authorities to these groups

- Nationally, there are structured groups/bodies in place that focus on anti-counterfeiting and related activities that may also go beyond the counterfeiting of medical products and similar crimes (**Belgium, Hungary, France**). In Belgium, this concerns the counterfeiting of medical products and food fraud. In Hungary, this concerns combating the wider trade in counterfeit products and has a specific working group on counterfeit medical products. In France, this concerns a joint law enforcement and industry group on laboratory analysis and the identification of online platforms promoting counterfeit medical products.

Promising Practices

- In **Belgium**, the Pharma-& Food Crime Platform ensures the national exchange of information and cooperation between health authorities, Customs and the police. It deals with cases of falsified medicines and food fraud.

- In **Hungary**, the National Board Against Counterfeiting (NBAC), which was established by Government Decree in 2008, involves the full spectrum of enforcement and commercial interests, including the public administration bodies, public prosecutors, police, National Tax and Customs Administration, trademark and copyright associations, interest groups of commerce and industry, and the enterprises concerned by counterfeiting. The NBAC has an Action Plan Against Counterfeiting and has a working group against the counterfeiting of medicinal products. This Action Plan fosters cooperation between the relevant bodies, and authorities, and organises common training, consultations, and the provision of information leaflets.

- In **France**, OCLAESP (Gendarmerie) and the industry G5 Group, involve an arrangement in which eight French laboratories, that have developed devices for identifying illicit sites of sale on the Internet, focus on information exchanges in detecting the trafficking of counterfeit medical products.

Recommendations

- Invites all Parties to review their legislation, policies and other measures to enhance and increase their ability to engage nationally and internationally with other authorities and bodies that are dedicated to combating counterfeit medical products and similar crimes.

4.6. National contact points for receiving and sending alerts on a suspect or confirmed counterfeit medical products between authorities

- The setting up of national contact points for the sending and receiving of alerts on a suspect or confirmed counterfeit medical product between authorities is in the context of a national strategy that facilitates this.

- Five Parties (**Armenia**, **Belgium, Croatia, Hungary, and Türkiye**) are assessed as having national contact points between at least the health product regulator

and the police. In two Parties (**Belgium, Croatia**) is it clear that this also includes the Customs service. While it is expected that other Parties also include Customs services in the points of contact, this was not stated by those Parties.

- While one Party (**Russian Federation**) has a national strategy, which is general to all industrial products, including medical products, and requires increased interaction between authorities. While this does not address the existence of contact points for the receiving and sending of alerts between authorities, it implies that this is the result of the increased interaction. This needs to be clarified to ensure that alerts are received and sent and involve all relevant authorities in relation to combating the counterfeiting of medical products and related crimes.

- Where it has not already been determined that a Party had a formal national strategy to combat counterfeit medical products and similar crimes, it is important to determine whether contact points for the purpose of receiving and sending alerts exist in any form. This is the case in two Parties (**France, Spain**) where it is evident from other data available that national contact points exist for sending and receiving alerts on counterfeit medical products between the authorities.

- While one Party (**Switzerland**) has not provided information on this issue, having the possibility to do so as the question was optional, it is evident from other data that it has a national scheme to address counterfeit medical products in relation to the MEDICRIME Convention and operates a contact point for the sending and receiving of alerts between national and cantonal authorities.

- It is assessed that in almost all Parties, the health product regulator is a key contact point for all authorities nationally in receiving and sending information and alerts on a suspected and counterfeit medical product, particularly with reference to regulatory quality defect reports, but not necessarily relating to criminal law matters.

- Only in one Party (**Russian Federation**) is there a review scheme, conducted by the State Commission and reporting to the Federal Government, to assess the effectiveness of measures to increase interaction between authorities. However, it is unclear in this case whether this assesses the effectiveness of a national contact point for receiving and sending alerts on counterfeit medical products and similar crimes.

Recommendations

- Urges all Parties to review their legislation and measures to provide within a national strategy or action plan on counterfeit medical products and similar crimes to stipulate the national contact points among all relevant authorities for the receiving and sending of alerts.

4.7. Points of contact specified for the international exchange of information relating to the counterfeiting of medical products that have different arrangements to other points of contact

- This part seeks to ascertain what specific arrangements exist for the international exchanges of information, such as medical product alerts and analytical reports from laboratory investigations. This is in the context that they are dedicated to this type of focus and are not general points of contact, such as for general medical product alerts or general crime alerts, as is the case with INTERPOL National Control Bureaus in the Parties, for the Europol equivalents.

- Five Parties (**Belgium, Croatia, Hungary, Russian Federation, Switzerland)** are assessed as having specified points of contact for the international exchange of information specific to counterfeit medical products and they specify the organizations with whom they engage: WHO MSMech SF, CoE CMED, both primarily focused on public health protection issues, and HMA WGEO (EU).

- Seven Parties (**Armenia, Cyprus, France, Morocco, Portugal, Spain, Türkiye**), whilst not providing information to support the assessment under this heading, are known from other information supplied, to also have contact points for the international exchange of information, though this requires clarification on whether the points of contact are specific or general in nature.

- It is assessed that in almost all Parties, the health product regulator is a key contact point for the international exchange of information relating to the counterfeiting of medical products, albeit focused on public health issues and not primarily on criminal law issues.

- Most Parties are assessed as engaging in the exchange of information relating to the counterfeiting of medical products and similar crimes during international operations, in particular, the INTERPOL coordinated Operation PANGEA. This also arises for Parties engaged with EUROPOL operations specific to this type of crime.

Recommendations

- Urge all Parties to review their legislation and measures to ensure that they have specified points of contact for the international exchange of information relating to the counterfeiting of medical products and similar crimes.

- Invites all Parties to ensure that all relevant authorities, including the health product regulator, police and customs service are involved in supporting the points of contact for the international exchange of information relating to the counterfeiting of medical products and similar crimes, including information on product alerts and the results of laboratory analysis for such products.

4.8. Legal basis for the exchange of information and transfer and receipt of data between bodies/countries

This part seeks to ascertain whether the exchange of information or transfer and receipt of data and evidence between bodies/countries is supported by legislation. The focus of this issue is mainly on the exchanges between countries and those between equivalent bodies in different countries. It may also include federal arrangements within countries. Exchanges in information or transfer and receipt of data and evidence require legal provisions to include all of the relevant authorities, and not be restricted to some authorities having obligations while others do not. It should be a mutual obligation.

- Almost all Parties **(Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have legislation to support the exchange of information or transfer and receipt of data and evidence between countries. This does not mean that the legislative basis in all of the Parties enables these activities to take place between all the Parties to the MEDICRIME Convention, including those who are not part of this monitoring report. One Party (**Armenia**) does not have legislation to underpin the existing exchange of information and the transfer and receipt of data and evidence between bodies and/or countries relating to counterfeit medical products, but has a planned Government Decree to cover this.

- The transfer of information between law enforcement on criminal matters of the Parties may be transferred in accordance with protocols established with INTERPOL, EUROPOL, and World Customs Organization.

- The legal basis for the transfer of information and data between authorities internally is clear in some Parties (**Hungary, Morocco, Russian Federation, Spain, Switzerland**), but is not specified by all Parties (**Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Portugal, Türkiye**). In **Belgium**, the obligation and legal authority for such activities clearly arises with the regulatory authority (FAMHP) but is not evident that the same obligations arise with the other relevant Belgian authorities providing information and data to FAMHP, notwithstanding that the transfer and sharing may exist in practice. In **Bosnia and Herzegovina**, the legal basis for these obligations and the extent to which they apply is not clear. Such legal obligations need to be clear to all relevant authorities.

Promising practices

- In the **Russian Federation,** in accordance with the Strategy on Combating Illicit Trafficking in Industrial Products in the Russian Federation for the period up to 2025, which includes counterfeit medical products, is supported by legislation. This provides for cooperation with international organizations whose activities are aimed, inter alia, at countering illicit trafficking in industrial

products, including the exchange of experience with foreign countries.

- In **Spain**, the exchange of information and personal data between law enforcement authorities must be subject to the applicable national and international laws and to bilateral or multilateral agreements signed between the respective governments. Where necessary, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL and police attachés, including joint investigations with those countries.

- **In Switzerland,** Swissmedic, the regulatory authority for medical products, became the national specific point of contact (SPOC) in accordance with Article 69, para. 4, Therapeutic Products Act (TPA) on 1 January 2019. Violations in connection with the use and dispensing of therapeutic products fall under the competence of the cantonal prosecution authorities. Swissmedic's Penal Division, the Office of the Attorney General (OAG) and the cantonal prosecuting authorities exchange information, thus ensuring uniform prosecution of violations relating to the TPA throughout Switzerland. The exchange of confidential data between the (federal and cantonal) enforcement authorities in Switzerland and between the federal enforcement authorities and foreign authorities/institutions is enabled by law, cf. Articles 63 and 64 TPA. In the international context, the prosecutor's offices in Switzerland fulfil mutual legal assistance in close cooperation with the Federal Office of Justice. The Federal Office of Police (FEDPOL) is the central agency for police co-operation which builds and maintains contacts between the cantonal police and law enforcement agencies and between them and international partners.

RECOMMENDATIONS:

- Urges **Armenia, and Bosnia and Herzegovina** to review their legislation to ensure that there is a clear legal basis for the exchange of information or transfer and receipt of data and evidence between bodies/countries.

- Invites all parties to review their legislation to ensure that the exchange of information and data relating to counterfeit medical products and similar crimes by all authorities that conduct such exchanges, both within the domestic and in international settings, are supported by legislation.

V. DETECTION

This part of the report considers detection measures in the context of times of pandemics. This is of particular concern having regard to the global experience during the COVID-19 pandemic and the expectation that both pandemics and epidemics will continue in times to come. While detection measures taken during a pandemic may be a development of detection measures already in existence, it is not guaranteed that such measures already exist in the pre-pandemic period or that they will be continued in the post-pandemic period.

The Convention envisages that detection measures will be adequate to the context, but not exclusive to times of crisis, as in pandemics. Therefore, measures taken in this regard are intended to be effective, appropriate, proportionate and sustainable.

Article 18 – Preventive measures 2. Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products

- This chapter aims to understand and appreciate the different measures that may be proactively taken during a pandemic to detect counterfeit medical products and prevent them from reaching patients.

- This concerns:

    - Identifying legislative or other measures to ensure that the industry can promptly report suspicions or detections of counterfeit medical products
    - Identifying market sampling programmes to detect counterfeit medical products on the market
    - The application of sampling programmes to cover public procurement programmes of medical products to detect counterfeit medical products in the public health system
    - Identifying legislative measures, that are different and separate to laws on intellectual property rights, to enable customs service to detect, detain and act on counterfeit medical products.

- The focus on detection flows from the Explanatory Report noting that "*The reason for the strong growth of this type of crime is clearly the relatively low risk of detection and prosecution compared with the potential high financial gains"*. In order to prevent and combat threats to public health, the overall purpose of the Convention, as provided by Article 1, the detection element is required as a central action. However, the term is not mentioned in the Convention, and only a few references are made in the Explanatory report. Yet, detection measures are central to the assurance of protecting public health and prosecuting offenders engaged in the counterfeiting of medical products and similar crimes.

- Both the Convention (Articles 17.2 and 3 and 18. 2 and 3) and the Explanatory Report focus on the necessity of cooperation measures between both public authorities and the private sector in preventing and combating the counterfeiting of medical products and similar crimes. The Convention foresees that all action in the detection of such products includes the dissemination of relevant information, including data collection, risk management, sharing of data and ensuring that the appropriate detection powers are available to those who require them. Specific reference is made for customs services in relation to providing powers that are separate and distinct in the protection of public health from intellectual property rights offences that protect individual economic rights.

5.1. Reporting by industry of suspicions and detections of counterfeit medical products and similar crimes (Article 18.2)

- This concerns any legislative or other measures to ensure that the industry can promptly report suspicions or detections of counterfeit medical products and similar crimes involving threats to public health, or to any particular authority. It also concerns whether there are any established or ad hoc procedures and processes in place for this reporting.

- The reporting by industry is not mentioned in either the Convention or in the Explanatory Report. It is a measure required to give effect to the provisions of Article 18.2 to ensure the safe distribution of medical products.

- Reporting of suspected or confirmed counterfeiting of medical products by industry to the regulator for health products arises for several Parties from regulatory licensing requirements (**Armenia, Croatia, Cyprus, France, Hungary, Portugal, Spain, Switzerland, Türkiye**). This mainly applies to medicinal products, active substances and excipients only in such cases, except for Switzerland which explicitly also includes medical devices. The reporting is mandatory in some cases (**Armenia, Cyprus, France, Hungary, Portugal, Switzerland, Türkiye**), although a more general obligation to report any crime coming to notice applies in one Party (**Bosnia and Herzegovina),** while, in only one case, it is an obligation for statutory professional bodies to report where they become aware of a criminal offence in the course of their professional duties **(Hungary).**

- Some Parties **(Belgium, Russian Federation, Switzerland)** focus on processes to push out to industry information concerning suspected or confirmed counterfeit medical products, using a rapid alert system or the regulatory authority website information. In these cases, the same information and alert systems may also facilitate reporting by industry, but this requires clarification.

- In two cases, it is noted that dedicated email addresses are provided to facilitate reporting (**Hungary, Spain**).

- While not specifically noted by the Parties, it is likely in most cases that the health product regulator has a clear and defined reporting system for the industry to report substandard and counterfeit medical products under the label of quality defect reports, while others, as noted above, have dedicated reporting systems for counterfeit medical products and similar crimes.

- It is assessed that in two cases (**Cyprus, France**) there are active reporting systems for reporting to law enforcement.

- In one Party (**France**), there is a system of reporting between law enforcement and certain manufacturing industry whose products have been the subject of counterfeiting. This is to improve the sharing and cross-checking of information to detect trafficking and counterfeiting of medical products.

- Reporting processes and procedures are provided by two Parties (**Spain, and Switzerland**). This may also arise where dedicated reporting email addresses are provided, but this is unclear.

Promising practices

- In **Cyprus**, manufacturers and marketing authorisation holders are obliged to report suspicions of falsified medical products where they obtain information from any source about falsified medical products where the legitimate product is associated with their activities.

- In **France**, the Central Office for the Fight against Environmental And Public Health/Office Central de lutte contre les atteintes à l'environnement et à la santé publique (OCLAESP) established a system with five major medical product manufacturing companies to share and enhance information cooperation to combat the counterfeiting and trafficking of medical products.

- In **Hungary and Spain**, a dedicated email address is provided by the health product regulators to facilitate industry report instances of a suspect and confirmed counterfeiting of medical products.

- In **Spain and Switzerland**, the health product regulator for medicinal products and medical devices (AEMPS and Swissmedic, respectively) in conjunction with the respective Ministry of Health, issues instructions to the industry on the reporting of a suspect or confirmed instance of counterfeiting of medicinal products.

Recommendations

- Urges **Armenia, Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, and Spain** to review their legislation in order to establish systems for reporting counterfeit medical devices, accessories, and parts and materials.

- Urges **Bosnia and Herzegovina** to review its legislation in order to establish a system for reporting by industry of a suspect or confirmed counterfeit medical product, active substance, excipient, and for accessories and parts and materials in relation to medical devices.

- Invites Parties, (except for **Hungary**, and **Switzerland** in relation to medicinal products only) to consider reviewing their legislation and measures to enhance the reporting by industry by the introduction of mandatory reporting and specifying to which authority the report be made on a suspect or confirmed counterfeit medical product, active substance, excipient, and for accessories and parts and materials in relation to medical devices.

5.2. Market sampling programmes to detect counterfeit medical products on the market (Article 18.1, 3.c)

- This concerns any legislative or other measures on the establishment of sampling and analysis programmes to detect counterfeit medical products on the market and to ascertain which authority has this responsibility. It seeks to determine whether the sampling and analysis programme is sustainable during times of pandemic having regard to the additional demands placed on analytical laboratories and testing services resulting from the impact of a pandemic. In order to understand the effectiveness of such legislation and measures, it seeks to identify any oversight arrangements of such measures.

- While market sampling programmes are not mandated by the Convention and not mentioned in it, nor in the Explanatory Report, this is a proactive measure to determine the extent, if any, to which counterfeit medical products are available on the market of the Party. This includes the distribution, wholesaling, and retailing levels. The absence of any such programme results in the Party relying on the reported suspect medical products by industry or by the public, and others. If market sampling programmes for risk-bearing medical products are not conducted, or not on a structured basis, then the Party may not be aware of the presence of counterfeit medical products on its market notwithstanding that it has not received any such reports from the market to date.

- It was noted that the absence of a medical device market sampling programme was based on the understanding that it was mainly medical device documentation that was falsified rather than the medical device itself, of which there were large numbers in circulation. While this may have some validity concerning falsified documentation, medical devices can also be falsified and found on the market where the documentation is not checked or where the documentation accompanying a counterfeit medical device is genuine. This lacuna creates a vulnerability for the protection of public health and enables criminal elements to evade detection and criminal prosecution.

- While many Parties, in particular, their medical product regulatory authorities, may already have laboratories available to them to test, examine or analyse the sampled medical product, this will usually be done to determine the quality of the medicinal product as regards sufficiency of active substance and compliance with labelling standards of medicinal products and to ensure compliance with the essential requirements and labelling for medical devices.

- A market sampling programme for both medicinal products and medical devices, including counterfeit products, exists in two Parties (**Russian Federation, and Türkiye**).

- A market sampling programme is assessed to exist for medicinal products only in five Parties (**Belgium, Bosnia and Herzegovina**, **Croatia, Portugal, Spain**), and for medical devices only in one Party (**Switzerland**). Switzerland suspended

its medical device sampling programme during COVID-19 due to the ad hoc testing of the pandemic-related to non-conforming medical devices. One Party (**Portugal**) operated the market sampling programme for counterfeit medical products between the customs service and the health products regulatory authority.

- There was no structured market sampling programme for either medicinal products or medical devices in five Parties (**Armenia, Cyprus, Morocco, France, Hungary**), with France and Hungary relying on participation in international programmes (INTERPOL's Operation Pangea, and World Customs Organization's Operation STOP, respectively) to detect counterfeit medical products in the market, including through unlicensed online outlets.

- One Party (**Switzerland**) has a structured market sampling programme for medical products from a quality perspective and considers that it can identify counterfeit medicinal products from such sampling.

- Outside of the COVID-19 pandemic, Hungary relies on the general market sampling programmes conducted by the Ministry of Innovation and Technology.

Recommendations

- Urges **France and Hungary** to review their legislation in order to implement structured market surveillance programmes for medical products.

- Invites **Armenia, Cyprus, Hungary and Morocco** to review their legislation in order to implement a structured market surveillance programme for medical products.

- Invites **Belgium, Bosnia and Herzegovina, Croatia, and Spain** to review its legislation in order to implement a structured market surveillance programme for medical devices.

5.3. Market sampling programmes for public procurement programmes of medical products to detect counterfeit products being used in the public health system (Article 18.2)

- This concerns legislation and measures established to provide for market sampling programmes for public procurement of medical products being used in the public health system and whether this includes sampling for counterfeit medical products. This is in the context of those medical products not being procured for supply or sale to the trade or public. It seeks to determine, in the absence of such programmes, whether there are arrangements to introduce them.

- Public procurement programmes are not specifically mentioned in either the Convention or in the Explanatory Report. As noted above in relation to the terms

'supplying' and 'offering to supply' (Article 6), these terms are understood in their widest sense and include the act of procuring.

- Procurement programmes intended for the public health systems that are not intended for supply or sale to the trade or public may escape the scrutiny of the medical product regulator's oversight. This increases the risk of counterfeit medical products infiltrating the public health system.

- Two Parties (**Portugal and Türkiye**) were assessed to have a specific inclusion for the sampling of the public procurement programme that excluded sale or supply to the trade or the public. While market sampling programmes exist in a number of the Parties (**Croatia, Spain**) that could facilitate the inclusion of the public procurement programmes without the need to adjust legislation or provide additional measures, they did not conduct such public procurement programmes sampling. In Spain, some medical devices used by healthcare practitioners in the public health system were routinely sampled for conformity with the essential requirements of the device.

- As there is no market sampling programme for medical products in five Parties (**Armenia, Cyprus, France, Hungary,** and **Morocco**), the inclusion of the public procurement programmes is not possible at this time. Switzerland plans to conduct a medical device sampling programme.

- The sampling programmes, as and where they currently exist, are conducted by the health product regulator of the Parties. They check for quality defects and not specifically for counterfeit medical products. Parties may consider that as counterfeit medical products contain quality defects then instances of counterfeiting of medical products would be detected in market sampling. This approach relies on the intensity of the sampling programme regarding the frequency of sampling and depts of checks conducted on the product. It is noted that medical products may only be sampled by the Parties once in five years, or more routinely 'for cause'.

Recommendations

- Urges **Armenia, Cyprus, France, Hungary,** and **Morocco** to review their legislation and measures in order to establish market sampling programmes on a sustainable basis that include public procurement programmes to detect counterfeit medical products that are not intended for sale or supply to the trade or the public.

- Invites Parties to ensure that market sampling programmes are extended to medical products to include a focus on detecting counterfeit medical products and not only on medicines or for quality defects generally.

5.4. Laws and policies to enable customs service to detect, detain and act on counterfeit medical products, as defined in Article 4. j of the Convention (Articles 1.a, 4.j, 18.3.a, c)

- This concerns legislation and measures established to enable the customs service to detect, detain and act on counterfeit medical products within the meaning of the Convention (Article 4.j definition) without having to rely on intellectual property rights whose focus is on the protection of private economic rights rather than public health. The Explanatory Report (paragraphs 20 and 26) clarifies that the Convention does not cover any issues related to the infringement of intellectual property rights in relation to the counterfeiting of medical products, active substances, excipients, parts and materials.

- Article 1 of the Convention provides for the criminalisation of certain acts. These are different and distinct from acts criminalising for different purposes. As the meaning of counterfeit in Article 4. j of the Convention is different from that of intellectual property meaning of counterfeit, this report seeks to understand whether the laws and policies of the Parties enable the customs service to take action without reference to a rights holder notwithstanding that the same medical product may also infringe intellectual property rights.

- Five Parties (**Hungary, Portugal, Russian Federation, Switzerland, Türkiye**) have legislation that empowers customs services to detect, detain and act on counterfeit medical products, as defined in Article 4. j of the Convention. In Hungary, this power is applicable to medicinal products and does not include medical devices.

- In three cases (**Belgium, Bosnia and Herzegovina, Croatia**), reliance is placed on general legislation, one of which is assessed as limited and inadequate for the customs service action as intended by the Convention.

- In Belgium, reliance is placed on the EU regulations (765/2008/EC) on accreditation and conformity regulations to control health and safety matters and the protection of consumers from risk-bearing products. While this is not specific to counterfeit medical products, Belgium uses this non-intellectual property approach for the customs service to act on counterfeit medical products. While this mechanism permits the customs service to act to protect public health, it is assessed as not using the meaning of counterfeit medical products as defined in Article 4. j of the Convention and inappropriate for the purposes intended by the Convention in this regard. As Belgium ratified the Convention in 2016, more specific legislation, policies and measures should be available to protect public health from counterfeit medical products.

- Reliance is placed in Bosnia and Herzegovina on the Basil Convention to control the transnational movement of hazardous waste (in this case, pharmaceutical waste, drugs and medicines). This is assessed as an inadequate and inappropriate response to the requirements of the MEDICRIME Convention to detect, detain and act on counterfeit medical products. As Bosnia and

Herzegovina ratified the Convention in 2020, more specific legislation, policies and measures should be available to protect public health from counterfeit medical products.

- In Croatia, reliance is placed on EU Regulation (952/2013, Article 47) laying down the Union Customs Code. This regulation enables Customs to cooperate with other competent authorities that have control functions relating to goods and with a view to having those controls performed, wherever possible, at the same time and place as customs controls. While this is not specific to counterfeit medical products, Croatia uses this general approach for the customs service to act on counterfeit medical products. While this mechanism permits the customs service to act to protect public health, it is assessed as not using the meaning of counterfeit medical products as defined in Article 4. j of the Convention and inappropriate for the purposes intended by the Convention in this regard. As Croatia ratified the Convention in 2020, more specific legislation, policies and measures in line with the Convention should be available to protect public health from counterfeit medical products.

- Two Parties (**Cyprus, France**) did not respond on this issue, having the possibility to do so as the question was optional.

Recommendations

- Urges all Parties, except the **Portugal, Russian Federation, and Türkiye** to review their legislation, policies and measures to enable their customs service to detect, detain and act on a counterfeit medical product, as defined by Article 4.j, different to the intellectual property meaning of counterfeit, without the need to refer to the rights holder, and specific to the offences intended by the MEDICRIME Convention.

VI. INVESTIGATION AND PROSECUTION

This section focuses on the ability to investigate and prosecute perpetrators of intentional offences related to the counterfeiting of medical products and similar offences, particularly during a pandemic.

- From a procedural perspective, it is established that investigations and prosecutions in this field are not subordinate to a complaint or may continue even in case of withdrawal of the complaint.

- It is relevant to highlight the importance of the specialisation and adequate training of persons, units and services in charge of criminal investigations in the area of counterfeiting of medical products and similar crimes involving threats to public health.

- A key aspect in the investigation and prosecution of offences related to the counterfeiting of medical products and similar crimes involving threats to public health is the concept of effective investigation which includes financial investigations, covert operations, controlled delivery and other special investigative techniques.

Article 15 – Initiation and continuation of proceedings

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn

Article 16 –Criminal investigations

1 Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

2 Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

Explanatory Report

Article 15 – Initiation and continuation of proceedings

106. Article 15 is designed to enable the public authorities to prosecute offences established in accordance with the Convention ex officio, without a victim having to file a complaint. The purpose of this provision is to facilitate prosecution, in particular by ensuring that criminal proceedings may continue regardless of pressure or threats by the perpetrators of offences towards victims.

Article 16 – Criminal investigation

107. The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.
108. Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamentalprinciples of their national law. The notion of "principles of national law" should be understood as also encompassing basic human rights, including those provided under Article 6 of the ECHR.
109. "Effective investigation" is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording "where appropriate", Parties are not legally obliged to apply any orall of these investigative techniques, but if a Party chooses to conduct investigations using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.
110. The ad hoc committee underlined that "controlled delivery" is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products andsimilar crimes. The measure of "controlled delivery" is already

foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances and the Second Additional Protocol to the European Convention on Mutual Legal Assistance in CriminalMatters (ETS No. 182).

6.1. The criminalisation of offences in order to enable effective investigation and prosecution

- This part seeks to ascertain the level of correspondence between the domestic laws of the Parties and the definitions of certain concepts included in the MEDICRIME Convention (Article 4).

- Additionally, this part aims to establish the correspondence between the internal criminal law of the Parties and the offences set up in Articles 5 to 8 of the MEDICRIME Convention.

- Finally, the section is oriented to specify the measures taken to sensitize manufacturers and suppliers of medical products to the consequences of the activities of legal persons related to medical products having regard to Article 11, MEDICRIME Convention.

6.1.1. Correspondence of the concept of "medical products" in domestic law to the definition in Article 4. a, MEDICRIME Convention

- In the majority of Parties **(France, Hungary, Russian Federation, Switzerland, Türkiye)** the concept of “medical products” in domestic law corresponds to the definition in article 4. a.

- In some Parties (**Belgium, Croatia, Spain**) the concept of “medical product” is not specifically included in domestic law. This results in having to integrate this concept by means of two different legal terms (medicinal products and medical devices).

6.1.2. Correspondence of the concept of "counterfeiting" in domestic law to the definition in Article 4. j, MEDICRIME Convention with regard to medical products.

- In the majority of the Parties **(Armenia, Belgium, Croatia, Cyprus, France, Hungary, Morocco, Russian Federation, Spain, Switzerland)** the concept of “counterfeiting” in domestic law corresponds to the definition in article 4.j.

- Nevertheless, the concept of “counterfeiting” is not used by any of the Parties in the field of defining the offences related to medical products and similar crimes involving threats to public health. Most of the Parties **(Belgium, Croatia, France, Hungary, Russian Federation, Switzerland),** refer to the concept of “falsification” in this field.

- The reason for this preference for the concept of « falsification/falsified » instead of « counterfeit, as defined by the Convention » in most Parties emanates from the association in many countries of the notion of « counterfeiting » with the protection of Intellectual Property Rights (IPR), and the influence of the WHO definition of falsification of medical products.

6.1.3. Measures taken to ensure that offences related to the counterfeiting of medical products, as defined in Articles 4. a. and 4. j, MEDICRIME Convention, are criminalised in accordance with Articles 5 and 6.

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye),** the internal laws provide for the criminalisation of the conducts included in Articles 5 and 6, MEDICRIME Convention.

- Nevertheless, in one Party **(Cyprus)** the criminalisation of such conducts has not been verified.

- In one Party **(Portugal)** the substantive criminal law provides for offences connected with Articles 5 and 6 MEDICRIME Convention but further actions are needed to achieve full compliance by the internal legislation with Articles 5 and 6 MEDICRIME Convention.

- The internal legal model for the criminalisation of these conducts varies from country to country. In some Parties **(Croatia, Hungary, Russian Federation, Spain)**, this is established exclusively via the Criminal Code while in others **(Belgium, France, Switzerland),** it is based on different domestic legislations with specific criminal law provisions.

6.1.4. Measures taken to ensure the criminalization of intentional offences referred to in Article 8 MEDICRIME Convention relating to medical products, as defined in Article 4. a.

- Most of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye)** have implemented at the internal level Article 8. a. of the MEDICRIME Convention.

- Two Parties **(Croatia, Hungary)** have also implemented at their internal level Article 8.b., MEDICRIME Convention (commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party).

- Some Parties **(Cyprus, Portugal)** have not achieved full compliance with Article 8 MEDICRIME Convention from the criminal law perspective.

6.1.5. Measures taken to ensure the criminalisation of intentional offences referred to in Article 7, MEDICRIME Convention relating to documents, as defined in Article 4. h, when committed in connection with medical products

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Portugal, Russian Federation, Spain, Switzerland)**, the internal laws provide for the criminalisation of the conduct included in Article 7 MEDICRIME Convention.

- The internal legal model for the criminalisation of these conducts varies from country to country. In some Parties (**Belgium, Croatia, Russian Federation, Spain),** a specific criminal offence has been created in the Criminal Code referring to the falsification of documents related to medical products or the use thereof while in others it is the general crime of falsification of documents already existing in the Criminal Code which applies **(Hungary** that made a reservation on the basis of Article 7.2 MEDICRIME Convention, **Portugal).**

6.1.6. Measures taken to proactively sensitize manufacturers and suppliers of medical products to the consequences of intervention/non-intervention by legal persons in the course of their activities related to medical products (Article 11).

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland),** the internal laws implement Article 11 MEDICRIME Convention.

- Some countries **(Cyprus, Türkiye)** have not implemented Article 11 MEDICRIME Convention.

PROMISING PRACTICES

- In the **Russian Federation**, during the pandemic, on the basis of Federal Law № 95-FZ dated 01.04.2020, Article 238.1 of the Criminal Code of the Russian Federation was supplemented with part 1, which provides for liability for "circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements using the mass media or information and telecommunication networks, including the Internet". These changes are due to the fact that in the context of the pandemic, online stores experienced an increased demand, which is vulnerable to being used by counterfeiters of medicines, offering medicines at a lower price, as well as medicines that are claimed to be effective in the treatment or prevention for a new coronavirus infection.

- In **Switzerland**, in administrative procedures in cases of the illegal manufacture and/or supply of medical products, it is regularly underlined that in the case of a further breach of the Therapeutic Products Act, a penal procedure will follow. Moreover, Swissmedic mentions in media releases, in

regular newsletters to media professionals (listing penalties which entered into force) and in specific answers to the media that infringements of the Therapeutic Products Act may be punishable.

Recommendations

- Urges **Bosnia and Herzegovina** to transpose the provisions of the MEDICRIME Convention into its internal criminal law as required by the Convention. Considers positive the establishment by the Ministry of Justice of **Bosnia and Herzegovina** of a working group to find adequate solutions that will eliminate the identified gaps and improve the current provisions of the Criminal Code of **Bosnia and Herzegovina** and the Code of Criminal Procedure of Bosnia and Herzegovina in order to harmonize criminal legislation in **Bosnia and Herzegovina**.

- Urges **Cyprus** and **Portugal** to ensure that offences related to the counterfeiting of medical products, as defined in Articles 4. a. and 4. j, MEDICRIME Convention, are criminalised in accordance with Articles 5 and 6.

- Urges **Cyprus** and **Türkiye** to guarantee that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products.

- Urges **Cyprus and Portugal** to criminalise the conducts established in article 8 MEDICRIME Convention.

- Urges **Armenia, Belgium, France, Hungary, Marocco, Russian Federation, Spain, Switzerland, and Türkiye** to analyse the level of implementation by the domestic law of Article 8. b, MEDICRIME Convention (« *Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7: (…), b. the commercial use of original documents outside their intended use within the legalmedical product supply chain, as specified by the domestic law of the Party*").

6.2. Investigation and Prosecution Framework

6.2.1. Dedicated National specialised investigation units

This part seeks to obtain information specifically related to the counterfeiting of medical products and similar offences involving threats to public health, on specialized national investigation services responsible for conducting criminal investigations, and/or coordinating and/or supervising criminal investigations conducted by other services/authorities (Article 16), including formal or informal inter-institutional commissions or structures.

- Certain Parties **(Belgium, Croatia, France, Morocco, Spain, Switzerland, Türkiye)** have established specialized national investigation services responsible for conducting criminal investigations, coordinating, supporting, and supervising criminal investigations conducted by other services/authorities.
- Other Parties **(Armenia, Bosnia and Herzegovina, Cyprus, Hungary, Portugal, Russian Federation)** have no specialized or specifically designated unit in this area in the police services.

RECOMMENDATIONS:

- Considers that **Armenia, Bosnia and Herzegovina, Cyprus, Hungary, Portugal,** and the **Russian Federation** take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.

6.2.2. Specialised prosecutors in the field of counterfeiting of medical products and similar crimes involving threats to public health

This part seeks to ascertain information on the existence of specialised prosecutors, specifying whether they intervene at the national or local level.

- Related to specialised prosecutors in the field of counterfeiting of medical products and similar crimes involving threats to public health, the general finding is that there is a lack of specialisation in this area, for investigation or prosecution **(Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, Türkiye)**

Promising Practices

- **Belgium** has specialised prosecutors in this area who function on a regional basis.
- **Switzerland** has specialised prosecutors at the federal level who support with guidance to cantonal prosecutors in this field.

Recommendations:

- Invites **Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Morocco, Portugal, Russian Federation, Spain, and Türkiye** to consider the opportunity of establishing specialized prosecutors in the field of counterfeiting medical products and similar crimes involving threats to public health.

6.3. Leadership and processes for coordinating the investigations

This part seeks to ascertain, with regard to investigations into counterfeit medical products and similar crimes involving threats to public health, the existing or planned process used to decide which investigative department/body is responsible or takes the lead for investigations in general or when they arise. Additionally, it is aimed to determine whether there is a different process or mechanism for coordinating the investigation of pandemic-related offences (Articles 16.2, 17.1 and 3. b)

6.3.1. Existing or planned process used to decide which investigative service/body is responsible or takes the lead for investigations

- The different Parties **(Belgium, Bosnia and Herzegovina, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** have either procedural rules or formal criteria in order to decide which investigative department or body is responsible or takes the lead for investigations in general or when they arise.

- In certain Parties **(Belgium, Croatia, France, Morocco, Spain, Switzerland)** specialized units to conduct criminal investigations, and/or coordinate and/or supervise criminal investigations conducted by other services/authorities or even the presence of specialized prosecutors in this field (only in the cases of **Belgium and Switzerland**) do exist.

Promising practices

- In **Belgium**, depending on the specifics of a case, the Prosecutor of the region where the infraction occurs or the Federal Agency for Medicines and Health Products takes the lead. The Prosecutors have to be notified of all cases even if they do not lead the investigation. The Federal Agency for Medicines and Health Products' Special Investigations Unit (SIU), investigate falsification of medicines and medical devices. The SIU inspectors are qualified with pharmaceutical or scientific degrees and are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and with other agencies, which is evaluated on a case-by-case basis) goes through the Pharma and Food Crime Platform.

- In **Switzerland**, the investigation body that takes responsibility for investigations of counterfeit medical products depends on the criminal jurisdiction to prosecute the case. The Swissmedic Penal Division is responsible for prosecuting perpetrators of violations relating to the manufacture, supply (including the import and export) and trafficking of counterfeit medical products, whereas violations in connection with the use and dispensing of counterfeit medical products fall under the jurisdiction of the cantonal prosecution authorities. If the import/export of counterfeit medical products also involves a violation of the Customs Act or the Value Added Tax Act, the Federal Customs Administration will prosecute and judge the offences (cf. Article 90, para. 1 Therapeutic Products Act). The Therapeutic Products Act provides for the possibility of combining the proceedings under either federal or cantonal jurisdiction if both federal and cantonal jurisdiction applies

in a criminal matter that falls within the scope of the Therapeutic Products Act's application (cf. Article 90, para. 4 TPA).

6.3.2. Processes or mechanisms for coordinating the investigation of pandemic-related offences

- Related to the processes or arrangements in place to coordinate crimes related to a pandemic (Articles 16.2, 17.1 and 3. b, MEDICRIME Convention) the majority of the Parties (**Armenia, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Portugal, Russian Federation, Switzerland, Türkiye**) did not establish any particular adaptation at this level.

- Only three Parties **(Belgium, Morocco, Spain)** have made special arrangements oriented to coordinate crimes related to pandemics.

PROMISING PRACTICES

- In **Belgium**, in the initial phase of the marketing of the vaccines, an ad hoc consultation platform was set up with the following participants: the Federal Agency for Medicines and Health Products (Special Investigation Unit; SIU), Federal Police and Justice. This was to anticipate possible falsified vaccines and to be able to take coordinated actions as quickly as possible.

- In Morocco, a special service order was established at the beginning of the COVID-19 pandemic to be supervised by an ad-hoc command post to monitor and coordinate the actions of all operational units and to centralise the data reported for analysis and guidance of the responses required according to the developing trends. This was aimed at improving the investigation of pandemic-related offences.

- In **Spain**, in relation to the coordination of investigations between different police forces, all operations, including those related to pandemic offences, are recorded in the Spanish Guardia Civil databases, which are crossed through the Intelligence Centre against Terrorism and Organised Crime (CITCO) with the databases of other police or customs forces. If there are overlaps between the entities under investigation, this body informs the units involved so that they can be coordinated.

- As well as actively participating in Operations PANGEA and SHIELD, when the pandemic began, a Service Order was drawn up to coordinate and enhance the investigation of offences linked to it, among all units.

6.4. Mechanisms for the public to transmit information to the investigation services

This concerns the mechanisms for the public to report information to the investigation services relating to the counterfeiting of medical products and similar crimes (this does not apply to pharmacovigilance reports or to product quality defects reports). This part also seeks to determine whether the report is made by telephone, email, online

platform or other means and whether it is a confidential notification system and if the effectiveness of this system is monitored.

- In **Armenia**, reporting is done by telephone, email, via an online platform, or other means, and this is a confidential report system.

- In **Croatia**, in order to report any suspicion of a quality defect, adverse drug reaction or counterfeit medicinal product, contact numbers and email addresses for the Rapid alert system are available on HALMED's website.

- In **France**, the National Gendarmerie set up a number of reporting tools aimed at the public allowing the latter to transmit any kind of information (digital platform, online pre-complaint, social networks ...). These tools are monitored and are subject to regular evaluations.

- In **Hungary**, an online reporting platform is available through police.hu, which is anonymous. In addition, the police receive notifications from the public by letter and e-mail. The Police have no information on the effectiveness of these systems. There is a dedicated email address for the purpose of reporting but information may be sent in any way and all methods are accepted. Mostly, the dedicated email address (hamisgyogyszer@ogyei.gov.hu) is used but there is a more confidential facility using electronic forms submitted by the official gateway. Email communication is more considered effective although less confidential as reports are mostly sent via unprotected email services.

- In the **Russian Federation**, citizens can leave a report in the appropriate section of the official website of Roszdravnadzor, as well as contacting the hotline by phone, or sending a complaint through the Unified Portal of Public Services (https://www.gosuslugi.ru/). Such reports, in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, must be considered. Compliance with the requirements of federal legislation is monitored by the Prosecutor General's Office. Citizens' reports and the timely response to them are recorded and monitored in a special closed subsystem of the Automated Information System of Roszdravnadzor.

- In **Türkiye**, complaints concerning counterfeit medicinal products and medical devices and similar crimes are received by the Presidential Communications Center (*CİMER*), Ministry of Health Communications Center (*SABİM*) and the official accounts of the Ministry of Health. Applicants are informed on their complaints within the framework of the relevant provisions. On the request of the applicant, personal information can remain confidential in applications made through the CİMER and SABİM systems. The registry systems for medicine and medical devices also have mobile applications through which people are able to check all such products purchased.

6.5. Collection of complaints about counterfeiting of medical products and similar offences at the national level

This part seeks to ascertain whether complaints about counterfeiting of medical products and similar offences are collected at the national level with a view to being

effectively registered, analysed and investigated or if they are dealt with on a case-by-case basis by individual investigative services/bodies.

- Five Parties **(Bosnia and Herzegovina, France, Portugal, Russian Federation, Spain)** deal with complaints about counterfeiting of medical products and similar crimes involving threats to public health on a case-by-case basis by individual investigative services and bodies.

- Six Parties (**Armenia**, **Belgium, Croatia, Morocco, Switzerland, Türkiye**) collate complaints about those offences at a national level.

Promising Practices

- In **Croatia**, the Agency for Medicinal Products and Medical Devices (HALMED) is responsible for the evaluation and processing of each report/information on suspected quality defects and counterfeited/falsified medicinal products received. Records are kept within the Agency's databases and archives. Handling of quality defects, suspicions of counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was considered to be in compliance with the defined legal requirements and set procedures.

- In **Switzerland**, reports on counterfeit medical products and similar crimes are collated on a national basis. Swissmedic maintains databases of reports regarding counterfeit medical products and similar crimes. Records of investigations and measures are kept. If a local authority is dealing with a case of a crime regarding a medical product in their own jurisdiction, the case will also be reported to Swissmedic.

6.6. Investigation of offences

This part seeks to ascertain whether all the offences set out in Articles 5 to 8 and Article 9 are investigated and whether they are subject to the lodging of a complaint and its maintenance (Article 15).

- In the majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** all prescribed offences in Articles 5-8 and 9 are investigated and not subject to a complaint being made and maintained.

- In all the aforementioned Parties if the investigation is the result of a complaint and the complaint is withdrawn the investigation can still continue.

- In these Parties, the criminal offences implemented at the internal level on the basis of (or equivalent to) Articles 5-8 and 9 MEDICRIME Convention are public offences which are prosecuted *ex officio*. Criminal proceedings may be initiated, even without the wishes of the injured parties, on the initiative of the Public Prosecutor.

Recommendation

- Urges **Bosnia and Herzegovina** to put in place the necessary measures in order to guarantee that all the offences set out in Articles 5 to 8 and Article 9 are investigated and that they are not subject to the lodging of a complaint and its maintenance.
- Urges Cyprus to ensure that investigations or prosecution of offences set out in Articles 5 to 8 and Article 9 MEDICRIME Convention are not subordinated to the lodging of a complaint.

6.7. Existence of an indicative list of offense with regard to the counterfeiting of medical products and similar offences involving threats to public health

- This part seeks to ascertain, with regard to the counterfeiting of medical products and similar offences threatening public health, if there is at the national level an indicative list of offences, taking into account Articles 5 to 9, 11 and 13 and other criminal legislation, to assist investigators in determining the legal basis and evidence necessary for the completion of investigations, in particular in times of pandemic when technical staff may not be immediately available (Article 16).

- In one Party **(Belgium),** the inspectors of the Special Investigation Unit of the Federal Agency for Medicines and Health Products (FAMHP) are specialised in this legislation and they assist police and Prosecutors when working in specific cases.

6.8. Discretion of the services/bodies responsible for investigating counterfeiting of medical products and similar offences to initiate and close an investigation without reference to a prosecuting authority or other authorities responsible for investigating counterfeiting of medical products, in accordance with the procedural rules of domestic law

- Only five Parties (**Armenia, Croatia, France, Hungary, Türkiye**) provided information on the discretion of the services responsible for investigating counterfeiting of medical products and similar offences to initiate and close an investigation without reference to a prosecuting authority or other authorities responsible for investigating the aforementioned crimes.

- Seven Parties (**Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Russian Federation, Spain, Switzerland**) did not provide information on this point, having the possibility to do so as the question was optional.

Promising practices

- In **Croatia** in all cases, according to the Criminal Procedure Law, investigating bodies must notify the prosecuting authority that a criminal investigation has begun. After completing the criminal investigation, investigating bodies also have to notify the prosecuting authority of the outcome of the criminal investigation.

- In **France,** the services and bodies responsible for investigations have the possibility of conducting investigations on their own initiative, but must automatically report to the judicial authority on the outcome of the investigation so that the Public Prosecutor can assess the follow-up to be given to it: initiate proceedings, implement an alternative procedure to prosecution in accordance with the provisions of articles 41-1, 41-1-2, or 41-2 of the Code of Criminal Procedure or dismiss the proceedings if the particular circumstances relating to the commission of the facts justify it (Article 40-1 of the Code of Criminal Procedure).

- In **Hungary** on the basis of Section 4(1) of CCP (Code of Criminal Procedure), the prosecution service or investigating authority shall launch a criminal proceeding *ex officio* if it becomes aware of a criminal offence subject to public prosecution. Furthermore, a member of an authority, a public officer, and, if required by law, a statutory professional body shall be obliged to file a crime report regarding a criminal offence subject to public prosecution if they becomes aware of it in their official competence or in their official capacity, respectively [Section 376(2) of CCP]. All grounds for dismissing the crime report (Section 381 of CCP) or for terminating the proceeding (Section 398 CCP) are determined by the CCP.

VII. SANCTIONS AND AGGRAVATING CIRCUMSTANCES

This section aims at identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating to offences committed in a pandemic.

According to Article 12, MEDICRIME Convention sanctions corresponding to the offences established by the Convention shall be effective, proportionate and dissuasive including criminal or non-criminal monetary sanctions. It is particularly relevant to point out that sanctions corresponding to offences created on the basis of Articles 5 and 6 MEDICRIME Convention shall include penalties involving deprivation of liberty that may give raise to extradition.

Particularly relevant is the precision, included in the Explanatory Report, related to article 8 MEDICRIME Convention, according to which “offences under Article 8 (manufacture and supply without authorisation or without the product being in compliance with regulatory requirements) cover a wide range of behaviour from more

formal violations of national administrative requirements to organised acts seriously affecting the health of individuals. While the seriousness is comparable to the behaviour criminalised by Articles 5, 6 and 7, minor violations of regulatory legal requirements (which may be of quite different nature and structure in Parties) may not always necessitate criminal sanctions in the technical sense. Fines of a non-criminal (i.e. regulatory or administrative) nature may therefore be considered sufficient in view of the overall context and structure of domestic law and penal sanctions."

Additionally, the internal laws of the Parties shall permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8 (Article 12. 2. a. and b. MEDICRIME Convention).

Related to the aggravating circumstances, Article 13 MEDICRIME Convention indicates six circumstances that, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration in determining the sanctions in relation to the offences established in accordance with the Convention.

Finally, Article 14 MEDICRIME Convention provides for the possibility to take into account final sentences passed by another Party in relation to offences of the same nature when determining the sanctions according to the offences established in accordance with the Convention.

Article 12 – Sanctions and measures

1 Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 and 6, when committed by natural persons, penalties involving deprivation of liberty that may give rise to extradition.

2 Each Party shall take the necessary legislative and other measures to ensure that legal persons held liable in accordance with Article 11 are subject to effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, and may include other measures, such as:

a temporary or permanent disqualification from exercising commercial activity;
b placing under judicial supervision;
c a judicial winding-up order.

3 Each Party shall take the necessary legislative and other measures to:

a permit seizure and confiscation of:

i medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;

ii proceeds of these offences, or property whose value corresponds to such proceeds;

b permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;

c take any other appropriate measures in response to an offence, in order to prevent futureoffences.

Article 13 – Aggravating circumstances

Each Party shall take the necessary legislative and other measures to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:

a the offence caused the death of, or damage to the physical or mental health of, thevictim;

b the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;

c the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;

d the offences of supplying and offering to supply were committed having resort to means of large-scale distribution, such as information systems, including the Internet;

e the offence was committed in the framework of a criminal organisation;

f the perpetrator has previously been convicted of offences of the same nature.

Article 14 – Previous convictions

Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

Explanatory Report

Article 12 – Sanctions and measures

84. This article is closely linked to Articles 5 to 8, which define the various offences that should be made punishable under domestic law. In accordance with the obligations imposed by those articles, Article 12 requires Parties to match their action to the seriousness of the offences and lay down sanctions which are "effective, proportionate and dissuasive". In the case of an individual committing an offence established under Articles 5 and 6, Parties must provide for prison sentences that can give rise to extradition. It should be noted that, under Article 2 of the European Convention on Extradition (ETS No. 24), extradition is to be granted in respect of offences punishable under the laws of the requesting and requested Parties by deprivation of liberty or under a detention order for a maximum period of at least one year or by a more severe penalty. Offences under Article 8 (manufacture and supply without authorisation or without the product being in compliance with regulatory requirements) cover awide range of behaviour from more formal violations of national administrative requirementsto organised

acts seriously affecting the health of individuals. While the seriousness is comparable to the behaviour criminalised by Articles 5, 6 and 7, minor violations of regulatory legal requirements (which may be of quite different nature and structure in Parties) may not always necessitate criminal sanctions in the technical sense. Fines of a non-criminal (i.e. regulatory or administrative) nature may therefore be considered sufficient in view of the overall context and structure of domestic law and penal sanctions.

85. Legal entities whose liability is to be established under Article 11 are also to be liable to sanctions that are "effective, proportionate and dissuasive", which may be criminal, administrative or civil in character. Paragraph 2 requires Parties to provide for the possibilityof imposing monetary sanctions on legal persons.

86. In addition, paragraph 2 provides for other measures which may be taken in respect of legal persons, with particular examples given: exclusion from entitlement to public benefits or aid; temporary or permanent disqualification from the practice of commercial activities; placingunder judicial supervision; or a judicial winding-up order. The list of measures is not mandatory or exhaustive and Parties are free to apply none of these measures or envisage other measures.

87. Paragraph 3 requires Parties to ensure that measures concerning seizure and confiscation of certain documents, goods and the proceeds derived from offences can be taken. This paragraph has to be read in the light of the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (ETS No. 141) as well as the Council of Europe Convention on Laundering, Search, Seizure and Confiscation ofthe Proceeds from Crime and on the Financing of Terrorism (CETS No. 198), which are based on the idea that confiscating the proceeds of crime is an effective anti-crime weapon.

As all of the offences related to the counterfeiting of medical products and similar crimes are undertaken for financial profit, measures depriving offenders of assets linked to or resulting from the offence are clearly needed in this field as well.

88. Paragraph 3 a provides for the seizure and confiscation of medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with the Convention or to facilitate their commission. Moreover, proceeds of the offences, or property whose value corresponds to such proceeds may be seized or confiscated.

89. The Convention does not contain definitions of the terms "confiscation", "instrumentalities", "proceeds" and "property". However, Article 1 of the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime provides definitions for these terms which may be used for the purposes of this Convention. By "confiscation" is meant a penalty or measure, ordered by a court following proceedings in relation to a criminal offence or criminal offences, resulting in final deprivation of property. "Instrumentalities" covers the whole range of things which may be used, or intended for use, in any manner, wholly or in part, to commit the criminal offences. "Proceeds" means any economic advantage or financial saving from a criminal offence. It may consist of any "property" (see the interpretation of that term below). The wording of the paragraph takes into account that there may be differences of national law as regards the type of property which can be confiscated after an offence. It can be possible to confiscate items which are (direct) proceeds of the offence or other property of the offender which, though not directly acquired through the offence, is equivalent in value to its direct proceeds ("substitute assets"). "Property" must therefore be interpreted, in this context, as any property, corporeal or incorporeal, movable or immovable, and legal documents or instruments evidencing title to or interest in such property.

90. Paragraph 3 b allows for the destruction of medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under the Convention.

91. Paragraph 3 c, addresses in general wording the various administrative measures that Parties may undertake in order to prevent future offences, including re-offending. The permanent or temporary ban on a perpetrator to carry on a commercial or professional activity in connection with which the offence was committed, or the withdrawal of professional licenses from perpetrators are

examples of what such measures could include.

Article 13 – Aggravating circumstances

92. Article 13 requires Parties to ensure that certain circumstances (mentioned in letters a.to f.) may be taken into consideration as aggravating circumstances in the determination ofthe sanction for offences established in this Convention. These circumstances must not already form part of the constituent elements of the offence. This principle applies to cases where the aggravating circumstances already form part of the constituent elements of the offence in the national law of the State Party.

93. By the use of the phrase "may be taken into consideration", the ad hoc committee highlights that the Convention places an obligation on Parties to ensure that these aggravating circumstances are available for judges to consider when sentencing offenders, although there is no obligation on judges to apply them. The reference to "in conformity with the relevant provisions of national law" is intended to reflect the fact that the various legal systems in Europe have different approaches to address those aggravating circumstances and permits Parties to retain their fundamental legal concepts.

94. The first aggravating circumstance (a) is where the offence caused the death of, or damage to the physical or mental health of, the victim. Given the inherent difficulties in linking the consumption of a medicinal product or the use of a medical device directly with the occurrence of a death, the ad hoc committee considered that in such cases, it should be up tothe national courts of the State Parties to assess the causal link between the conducts criminalised under the Convention and any death or injury sustained as a result thereof.

95. The second aggravating circumstance (b) is where the offence was committed by personsabusing the confidence placed in them in their professional capacity. This category of personsis in the first line obviously health professionals, but the application of the aggravating circumstance is not restricted to health professionals.

96. The third aggravating circumstance (c) is where the offence was committed by persons abusing the confidence placed in them as manufacturers and suppliers.

97. The fourth aggravating circumstance (d) is where the offences of supplying and offering to supply are committed through the use of large-scale distribution, including through informationtechnology systems. The ad hoc committee found that the use of information systems,including the Internet, for supplying counterfeit medicinal products and the supply and offering to supply thereof without authorisation is one of the most worrying and serious aspects of counterfeiting of medical products and similar crimes today. Given the immense outreach provided by the Internet, counterfeit, and hence dangerous, medical products are now being spread all over the world at an alarming rate, At the same time, due to problems of jurisdiction, it has become increasingly difficult to get at the criminals behind various Internet sites, offering cheap (i.e. mostly counterfeit) medicines or other medical products.

98. The fifth aggravating circumstance (e) is where the offence involved a criminal organisation. The Convention does not define "criminal organisation". In applying this provision, however, Parties may take their line from other international instruments which define the concept. For example, Article 2(a) of the United Nations Convention against Transnational Organised Crime defines "organised criminal group" as "a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences established in accordance with this Convention, in order to obtain, directly or indirectly, a financial or other material benefit". Recommendation Rec(2001)11 of the Committee of Ministers to member states concerning guiding principles on the fight against organised crime and the EU Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime give very similar definitions of "organised criminal group" and "criminal organisation".

99. The sixth aggravating circumstance (f) is where the perpetrator has previously been convicted of offences of the same nature as those established under the

Convention. By including this, the ad hoc committee wanted to signal the need to make a concerted effort to combat recidivism in the low risk – high gain area of counterfeiting of medical products and similar crimes.

Article 14 – Previous convictions

100. Counterfeiting of medical products and similar crimes are more often than not perpetrated transnationally by criminal organisations or by individual persons, some of whom may have been tried and convicted in more than one country. At domestic level, many legal systems provide for a different, often harsher, penalty where someone has previous convictions. In general, only conviction by a national court counts as a previous conviction. Traditionally, previous convictions by foreign courts were not taken into account on the grounds that criminal law is a national matter and that there can be differences of national law, and because of a degree of suspicion of decisions by foreign courts.

101. Such arguments have less force today in that internationalisation of criminal-law standards – as a pendent to internationalisation of crime – is tending to harmonise different countries' law. In addition, in the space of a few decades, countries have adopted instrumentssuch as the ECHR whose implementation has helped build a solid foundation of common guarantees that inspire greater confidence in the justice systems of all the participating states.

102. The principle of international recidivism is established in a number of international legal instruments. Under Article 36 paragraph 2 (iii) of the New York Convention of 30 March 1961 on Narcotic Drugs, for example, foreign convictions have to be taken into account for the purpose of establishing recidivism, subject to each Party's constitutional provisions, legal system and national law. Under Article 1 of the Council Framework Decision of 6 December 2001 amending Framework Decision 2000/383/JHA on increasing protection by criminalpenalties and other sanctions against counterfeiting in connection with the introduction of the euro, European Union member states must recognise as establishing habitual criminality final decisions handed down in another Member state for counterfeiting of currency.

103. The fact remains that at international level there is no standard concept of recidivism andthe law of some countries does not have the concept at all. The fact that foreign convictions are not always brought to the courts' notice for sentencing purposes is an additional practical difficulty. However, in the framework of the European Union, Article 3 of the Council Framework Decision 2008/675/JHA of 24 July 2008 on taking account of convictions in the member states of the European Union in the course of new criminal proceedings has established in a general way – without limitation to specific offences – the obligation of taking into account a previous conviction handed down in another (EU Member) state.

104. Therefore Article 14 provides for the possibility to take into account final sentences passed by another Party in assessing a sentence. To comply with the provision Parties may provide in their domestic law that previous convictions by foreign courts are to result in a harsher penalty. They may also provide that, under their general powers to assess the individual's circumstances in setting the sentence, courts should take those convictions into account. This possibility should also include the principle that the offender should not be treated less favourably than he would have been treated if the previous conviction had been anational conviction.

105. This provision does not place any positive obligation on courts or prosecution services totake steps to find out whether persons being prosecuted have received final sentences from another Party's courts. It should nevertheless be noted that, under Article 13 of the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30), a Party's judicial authorities may request from another Party extracts from and information relating to judicial records, if needed in a criminal matter. In the framework of the European Union, the issues related to the exchange of information contained in criminal records between member states are regulated in two legal acts, namely Council Decision 2005/876/JHA of 21 November 2005on the exchange of information extracted from the criminal record and Council Framework Decision 2009/315/JHA of 26 February 2009 on the organisation and

content of the exchangeof information extracted from the criminal record between Member states.

7.1. Seizure and confiscation

This part seeks to determine whether the internal laws of the Parties permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8 (Article 12. 2. a and b).

- In all Parties **(Armenia, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, France, Hungary, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye),** the internal laws permit the seizure, confiscation and disposal, including the destruction of medical products and other materials and instrumentalities employed to the commission of the offences established in Articles 5-8, MEDICRIME Convention.

- Some Parties **(Belgium, Russian Federation, Spain)** have legal dispositions which specifically refer to the seizure, confiscation and disposal, including destruction, of medical products and other instrumentalities used to commit the offences described in Articles 5-8, MEDICRIME Convention. In the rest of the aforementioned Parties which have provided information on this topic (**Bosnia and Herzegovina, Croatia, France, Hungary, Portugal, Switzerland, Türkiye)** seizure, confiscation and disposal in connection with offences established in Articles 5-8, MEDICRIME Convention falls under general dispositions of the respective Criminal Codes or other laws of the Parties, which allow those measures for a wide range of criminal offences.

Promising Practices

- In **Spain** the reform implemented by Organic Law 1/2015 of 30 March 2007 introduced a new Article 362 sexies into the Criminal Code, which provides for the confiscation of substances, objects, products, assets, media, instruments and gains, of all the previous articles of the Chapter ("On felonies against Public Health", where the offences transposing to the internal law Articles 5-8, MEDICRIME Convention are included). This reflects the requirements of Article 12 (3) (a) of the MEDICRIME Convention which requires the Parties to adopt the necessary legislative measures to allow freezing and confiscation.

7.2. Policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products

This part seeks to ascertain whether there are, at the internal level, policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering,

for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming.

- No Party provided information about the existence of particular policies intended to address such matters, having the possibility to do so as the question was optional.

7.3. Subordination of offences in Articles 5-9 MEDICRIME Convention to other criminal law offences

This part seeks to explore whether there is a policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products.

- Eight Parties **(Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Russian Federation, Spain, Switzerland, Türkiye)** did not provide information on this aspect, having the possibility to do so as the question was optional.

  - In three Parties, (**Armenia, Croatia, France**), there is no subordination at this level.

  - In two Parties (**Belgium, Hungary**) such subordination can exist. In **Belgium**, such subordination can exist when the other offences (for example, trafficking of controlled substances, and criminal organisations) are still more severely punished. In **Hungary**, subordination can exist depending on the circumstances of the special case. Usually, the concurrence of criminal offences can be determined, e.g. counterfeit medicines and intellectual property offences.

7.4. Specific sanctioning policy in the field of offences related to counterfeit medical products and similar crimes

This part seeks to determine whether there is a specific sanctioning policy in the field of offences related to counterfeit medical products and similar crimes generally, with specific reference to Article 13 circumstances in so far as they do not already form part of the constituent elements of the offence, and if so, whether the fact that the offence occurred during a pandemic is considered as an aggravating circumstance.

- The majority of the Parties **(Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Spain, Switzerland, Türkiye)** have implemented at the internal level the obligations set up by Article 13, MEDICRIME Convention that indicates six aggravating circumstances which, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration in determining the sanctions in relation to the offences established in accordance with the Convention.

- Different models of implementation of the aggravating circumstances established by Article 13, MEDICRIME Convention do exist. In certain Parties, (**Belgium, Spain, France**) specific aggravating circumstances for the offences related to counterfeit medical products and similar crimes are legally set; in other Parties (**Croatia, Hungary**), some of these circumstances give raise to qualified forms of offences and therefore are constituent elements of the respective offences and only the rest of the circumstances work specifically as aggravating circumstances. Finally, in another Party (**Switzerland**) the reference to the general aggravating circumstances (applicable to the different offences included in the Criminal Code) is considered sufficient in order to cover the spectrum of Article 13, MEDICRIME Convention.

- No Party reported the existence of a legal disposition at the internal level considered as an aggravating circumstance the commission of the offences related to counterfeit medical products and similar crimes during a pandemic. In one case (**Russian Federation**), and in accordance with paragraph "L" of Part 1 of Article 63 of the Criminal Code of the Russian Federation, an aggravating circumstance is the commission of a crime in a state of emergency, natural or other public disaster, as well as during mass riots, in conditions of an armed conflict or in case of war.

Recommendation

- Urges **Bosnia and Herzegovina, Cyprus, Morocco, and Portugal** to implement at the internal level the aggravating circumstances referred in Article 13, MEDICRIME Convention in so far as they do not already form part of the constituent elements of the offences.

7.5. Removal of professional status

This part seeks to ascertain whether and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article 13. c).

- Seven Parties (**Armenia, Belgium, Croatia, France, Hungary, Russian Federation, Türkiye**) have legal provisions to remove the professional status of both natural and legal persons.

- Six Parties **(Bosnia and Herzegovina, Cyprus, Morocco, Portugal, Spain, Switzerland)** did not provide information on this matter, having the possibility to do so as the question was optional.

Promising practices

- In **Belgium**, related to legal persons, the manufacturers and distributors are subject to licensing arrangements according to the Law of the 25th of March 1964 on Medicines. The Royal Decree of the 14th of December 2006 (the implementing decree of this law) lists all the obligations of the license holders. If they commit infringements, these licenses can be suspended or revoked. Moreover, they can also be prosecuted for these infringements.

- In **Croatia**, the removal of professional status is provided for by various Acts: Articles 7 (termination of the right to practice medicine) and 8 (unworthiness to perform medical activity) Act on Medicine; Article 29, Act on Pharmacy (revocation of the master's degree in pharmacy from independent work); and Article, 80 Medicinal Products Act (cancellation of the manufacturing authorization).

- In **France**, for natural persons, Article 131-6 15° of the Criminal Code provides, as an alternative penalty to imprisonment (including the conduct referred to in the MEDICRIME Convention), that there can be, at the court's discretion, a prohibition for a period of up to five years, from exercising a commercial or industrial profession, from directing, administering, managing or controlling in any capacity, directly or indirectly, on their own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Where the law so provides, natural persons may also incur the additional penalty of prohibition, in accordance with the procedures laid down in Article 131-27 of the Criminal Code, either from exercising a public function or from exercising the professional or social activity in the exercise of or in connection with the exercise activity of which the offence was committed, or from exercising a commercial or industrial profession, from directing, administering, managing or controlling in any capacity, directly or indirectly, for their own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Similarly, legal persons declared criminally liable, under the conditions laid down in Article 121-2 of the Criminal Code and as provided for by law, may also be sentenced to an additional penalty of dissolution and a prohibition mentioned in 2 ° of Article 131-39 of the Criminal Code relating to the activity in the exercise or on the occasion of the exercise of which the offence was committed.

- In **Hungary**, disqualification from a profession (Section 52-53 of CC) is another punishment which can be imposed next to imprisonment. In connection with legal persons, according to Section 3 of Act CIV of 2001 on the criminal measures applicable against legal persons if the court imposes punishment on the person committing the criminal offence defined in Article 2 or applies reprimand or probation against this person,

orders confiscation or forfeiture of assets, it may apply the following measures against the legal person:

a) winding up the legal person,
b) limiting the activity of the legal person,
c) imposing a fine.

- In the **Russian Federation**, one of the criminal punishments provided (as an additional one), *inter alia* for the circulation of falsified, substandard and unauthorized medicines, medical devices and the circulation of falsified nutritional supplements (Article 238.1 of the Criminal Code of the Russian Federation), is deprivation of the right to hold certain positions and be engaged in certain activities, prohibition to hold positions in the public service, in local self-government authorities, or to be engaged in certain professional or other activities.

VIII. DATA COLLECTION

8.1 Data Collection for the purpose of observing and evaluating counterfeit medical products or for another purpose (Article 17.3.a. and b)

This chapter concerns the effective collection, collation and analysis of data that can support combating counterfeit medical products and similar crimes involving threats to public health in a pandemic, and more generally.

The Convention or the Explanatory Report do not directly deal with the issue of data collection. Article 17 provides the direction required for the need to receive and collect information and data at all levels and in cooperation with the private sector and civil society. It also requires the sharing and exchange of data between the authorities, health authorities, customs, police and other competent authorities.

Article 17

3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:

a. receiving and collecting information and data, including through contact points, at
national or local levels and in collaboration with the private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;

b. making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.

OMCL Network[11] of the Council of Europe: General Document PA/PH/OMCL (09) 87 R5

[11] OMCL Network is a network of official medicines control laboratories funded by the Council of Europe and the European Union and implemented by the Council of Europe through its European Directorate on the Quality of Medicines and HealthCare (EDQM). OMCL Network - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)

- The OMCL Network supports the implementation of this Article (Article 17) at a practical and technical level because it has functioning information-sharing tools already in place that facilitate the rapid dissemination of information and data on falsified medicines between OMCLs and Competent Authorities.

- The Competent Authorities in turn make such information available to local law enforcement, customs and other governmental agencies, when necessary, and this leads to a more co-ordinated and collaborative approach between these key stakeholders in relation to dealing with falsified medicine.

The stipulated aim of Article 17, cooperation, is dealt with separately in Chapter II of this report. It does not mention data collection for the purpose of analysis and the Explanatory Report does not provide an indication as to why data needs to be collected in a systematic manner.

In order for policy formulation relative to legislative drafting, and the development of measures leading to the effective prevention, detection and investigation of counterfeiting of medical products and similar crimes, data must be available, collected in a systematic and standard form, reliable and useful. It supports the health products regulatory authority to ensure the continued development in maintaining a safe distribution of medical products and the protection of the public health system.

8.1.1. The collection of data in the normal course of activity and its purpose

- Data collection relating to falsified medical products and similar crimes has been assessed not to be of a high priority among the Parties included in this report, except for three (**Armenia, Belgium, Russian Federation**). **Armenia** collects data in the normal course of business. Such data is published and all data is archived. It is unclear from the information provided to what extent this includes data on counterfeit medical products or whether it concerns medical products generally. This requires clarification. Belgium collects the data for risk management purposes and the health product regulator's decision-making. The Russian Federation's Ministry of the Interior collects data on all crimes for law enforcement purposes and sharing with other relevant authorities.

- One other Party (**Croatia**) has made inroads into data collection in relation to counterfeit medical products and similar crimes. It includes the routine collection of both unanalysed medical products from law enforcement operations and those medical products analysed by the health product regulator, and this is done for the purpose of public health protection.

- One Party (**Hungary**), the Police service maintains a database recording all criminal activities, including data on analysis.

- Eight Parties (**Bosnia and Herzegovina, Cyprus, France, Morocco, Portugal, Spain, Switzerland, Türkiye**) did not submit any information on any aspect of data collection under this heading, having the possibility to do so as the question was optional.

- It is stressed, in this context, that in the absence of data collection, decision-making and policy formulation toward the protection of public health and the

assignment of resources for the investigation and prosecution of offences cannot be based on empirical evidence. This results in weakening efforts to combat counterfeit medical products and similar crimes and may fail to convince policymakers and the legislature of the need for action in this area of crime.

8.1.2. The collection of data specific to the COVID-19 pandemic period

- Two Parties (**Belgium, Russian Federation**) collected data and developed reports specifically during the pandemic specific to medical products. Belgium generated these reports on a more regular basis due to the rapid change in the profile of the medical products observed in postal packages during this period. In both cases, the focus was on the protection of public health by the health product regulator. One Party (**Armenia**) collected data irrespective of the COVID-19 pandemic.

- No other Party provided any information in this context relating to data collection, having the possibility to do so as the question was optional.

Promising Practice

- **Belgium** recorded data and generated COVID-19-related analyses and reports on a more regular basis due to the rapid change in product profile of counterfeit medical products observed in the postal system.

8.1.3. Mechanisms established for data collection

- Two Parties (**Belgium, Russian Federation**) established mechanisms that record counterfeit medical products. Belgium included the creation of external characteristics and parameters relating to the trafficking of counterfeit medical products in conjunction with Customs.

- One Party (**Hungary)** specified that the police database contains the mechanism for data collection relating to all crimes and not specifically to counterfeit medical products and similar crimes.

- One Party (**Armenia**) specified that data is collected by the health product regulatory authority by Government Decree. One Party (**Türkiye**) specified that it collected data based on Rapid Alert System and Drug Alert System. This does not clarify whether this includes counterfeit medical products or if it does, whether it classifies the data as counterfeit products or as quality defects. This requires clarification.

- No other Party provided any information in this context related to the mechanism established for data collection, having the possibility to do so as the question was optional.

8.1.4. Availability of relevant data collected, reports and analysis made, in particular, that relating to the COVID-19 pandemic

- One Party (**Armenia**) reported that the data is available but did not provide it.

- No Party provided relevant data collected, in particular, that relating to the COVID-19 pandemic, having the possibility to do so as the question was optional.

- No reports or analyses were conducted in this context.

8.1.5. Sharing with relevant authorities of data and relevant reports based on such data

- Four Parties (**Armenia, Belgium, Russian Federation, Türkiye**) share data and reports based on them between law enforcement and the health products regulator. Belgium, where relevant, also shares with EUROPOL, and other EU regulatory competent authorities for medical products.

- One Party (**Croatia**) shares data and reports with the Council of Europe (EDQM/OMCL/CMED), in particular during the COVID-19 pandemic.

- Eight Parties **(Bosnia and Herzegovina, Cyprus, France, Hungary, Morocco, Portugal, Spain, Switzerland**) provided no relevant data in this context, having the possibility to do so as the question was optional.

Recommendations

- Urges the Parties that have not reached this stage to review their legislation, policies and measures ensuring designated mechanisms exist or adapt existing data collection systems to take account of the need to collect and analyse data that can support the combating of counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Invites Parties, where specific mechanisms are not already in place, to ensure that existing data collection mechanisms used for other purposes are able to produce accurate and reliable data on the phenomenon of counterfeit medical products and related crimes.

- Invites Parties that have not reached this stage, for the purpose of analysis, evaluation and reporting related to counterfeit medical products and similar crimes during the COVID-19 pandemic period, to ensure the separation from data already collected in the normal course of activity.

- Invites Parties to establish a comprehensive system of reporting of cases of counterfeit medical products, as described in Article 4.j of the Convention, and similar crimes to ensure completeness of data collected

- Invites Parties to review their legislation, policies and other measures to make the reporting to a specified central authority of suspect counterfeit medical products mandatory by authorities and the industry for the purpose of data recording, incident recording, and for public health and criminal investigation.

- Invites Parties to ensure that the terminology contained in the MEDICRIME Convention, and that contained in other legislation where relevant data is already collected, is compatible in meaning. This will ensure that data may be used to measure the incidence of counterfeit medical products and similar crimes as intended by the MEDICRIME Convention.

- Invites Parties to share data collected and analysed among their domestic authorities and with relevant authorities of other Parties and with the relevant international organizations.

- Invites Parties to appoint a national authority with providing periodic reports on aggregated data and recording of counterfeit medical products, in accordance with the meaning of counterfeit in Article 4.j of the Convention, and similar crimes, as intended by Article 8 of the Convention.

- Invites Parties to contribute to and make use of the General European Official Medicines Control Laboratories Network (GEON) of the Council of Europe/EDQM to support the pooling of technical data in relation to counterfeit medical products which will support the fostering of the exchange of data and results of analysis of counterfeit and other illicit medicines.

IX. CONCLUSIONS AND RECOMMENDATIONS

a) Conclusions

- The majority of the Parties made efforts in particular areas to give effect to the MEDICRIME Convention during the COVID-19 pandemic, in particular, in increasing awareness among the public of counterfeit medical products related to COVID-19 and the risks associated with procuring medical products from unauthorised online sources.

- The challenges posed by a pandemic were evident in the preparedness of Parties in some areas such that it disrupted their continued ability to detect and prevent counterfeit medical products and similar crimes. This arose, in particular, in disruptions to training facilitation to all those who required it. The challenges were exacerbated by the Parties not recognising that public and private procurement of medical products not intended for the trade or sale to the public was a weak link in the protection of public health from counterfeit medical products, in particular, during times of pandemics.

- While the Parties have developed legislation and measures in place in several critical areas, which apply equally to a pandemic and non-pandemic situations alike, such as the protection of victims, prohibitions on the online sale of counterfeit medical products, and areas related to cooperation, both for information sharing and investigations, the absence of review mechanisms challenges the effectiveness of the measure in place to address the protection of public health and the investigation of counterfeit medical products and similar crimes. This becomes more critical in times of major crises, such as a pandemic.

- The absence of coordinated data collection and analysis systems is a weak point that hampers the ability of policymakers to assess the extent of incidences of counterfeit medical products and similar crimes. This area was not well responded to by the Parties in this monitoring round, but could have resulted from this being an optional question for Parties.

- In general, the conducts included in Articles 5-8 MEDICRIME Convention have been criminalised in the majority of Parties. Nevertheless, to guarantee this level of protection in all Parties is key in order to ensure a sanctioning policy at this stage coherent with the articles of MEDICRIME Convention and to establish a certain homogeneity in the criminal framework applicable to these offences. Only on this legislative basis, further steps in the fight against the counterfeit of medical products and similar crimes can be reached.

- The MEDICRIME Committee noted concerns that the Parties did not always in their responses either interpret the monitoring round questions in the questionnaire as intended or did not apply these to times of pandemics.

- Furthermore, the Committee noted that optional questions were responded to by some Parties. For other Parties, it was considered that the legislation and measures were in place by the Party that would enable it to respond, should they have chosen to do so. These matters weaken the ability of the monitoring

round to report comprehensively on the protection of public health through the MEDICRIME Convention in times of pandemics.

b) Recommendations

Main recommendations emerging from the report concerning the majority of Parties:

As to the policies, strategies, plans and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics.

The MEDICRIME Committee:

- Urges the Parties to ensure that policies, strategies, and measures are provided for the training of those involved in public and private procurement programmes for medical products.

- Urges the Parties to develop contingency plans, strategies, and other measures to provide training in critical procurement and distribution areas of medical products with a view to preventing counterfeit medical products and similar crimes from arising when their systems, resources, and priorities are under stress, including during pandemics.

- Urges the Parties to implement legislation, plans, strategic and other measures to provide training in specialist investigative techniques to specialist units/bodies in the investigation of counterfeit medical products and related crimes, where appropriate.

- Urge Parties to undertake awareness-raising campaigns for those engaged in the procurement of medical products to close this gap in protecting public health.

- Urges Parties to ensure that arrangements are put in place for all relevant sectors, including those mentioned in Article 18.1, 2, and 3 of the Convention, that handle medical product waste to be included in awareness-raising campaigns.

As to identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products

The MEDICRIME Committee:

- Urges the Parties to issue reports on the measures, policies, and strategies taken to the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products.

- Urges all Parties to review their legislation and measures to record instances of the provision by civil society to the general public on awareness-raising campaigns and programmes on the risks arising from procuring and consuming counterfeit medical products.

As to the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation

The MEDICRIME Committee:

- Urges all Parties to put in place a national strategy or action plan to support cooperation and information exchange to enable the effective investigation to combat counterfeit medical products and similar crimes involving threats to public health.

- Urges all Parties to have a clear legislative scheme to support a national strategy or action plan that enables cooperation and information exchange for the effective investigation of counterfeit medical products and similar crimes involving threats to public health.

- Urges the Parties to make use of Memorandums of Understanding and Data Sharing Agreements to the fullest extent among the relevant national authorities, and where appropriate with equivalent bodies in other countries and with relevant international organizations in combating counterfeit medical products and similar crimes.

- Urges the Parties to ensure, in order to facilitate the effective investigation of counterfeit medical products, that cooperation and information-sharing arrangement involve civil society, industry, service providers, e-commerce, and social media platforms, at a minimum.

- Urges Parties to implement clear measures in relation to cooperation and information exchange to decide on which authority takes the lead and how participation in operational plans are decided.

As to the understanding and appreciation of the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and to prevent them from reaching patients

The MEDICRIME Committee:

- Urges the Parties to review their legislation and measures in order to establish systems for reporting suspect or actual counterfeit medical devices, accessories, and parts and materials.

- Urges all Parties to review their legislation, policies, and measures to enable their customs service to detect, detain and act on a counterfeit medical product, as defined by Article 4. j, different to the intellectual property meaning of counterfeit and without the need to refer to the rights holder.

As to the ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic

The MEDICRIME Committee:

- Urges the Parties to analyse the level of implementation by the domestic law of Article 8.b MEDICRIME Convention (« Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7: (…) b. the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party").

As to the effective collection, collation, and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general

The MEDICRIME Committee:

- Urges the Parties to review their legislation, policies, and measures to designate mechanisms to set up or adapt existing data collection systems to take account of the need to collect and analyse data that can support the combating of counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

- Urge the Parties to conduct effectiveness reviews on legislation and measures deployed to protect public health through the MEDICRIME Convention in times of pandemics and generally.

Appendix 1- State of signatures and ratifications of the MEDICRIME Convention

	Signature	Ratification	Entry into force
	Members of Council of Europe		
Albania	17/12/2015	06/06/2016	01/10/2016
Andorra			
Armenia	20/09/2012	05/02/2016	01/06/2016
Austria	28/10/2011		
Azerbaijan			
Belgium	24/07/2012	01/08/2016	01/11/2016
Bosnia and Herzegovina	04/12/2015	18/09/2020	01/01/2021
Bulgaria			
Croatia	03/09/2015	20/09/2019	01/01/2020
Cyprus	28/10/2011	05/09/2023	01/01/2024
Czech Republic			
Denmark	12/01/2012		
Estonia			
Finland	28/10/2011		
France	28/10/2011	21/09/2016	01/01/2017
Georgia			
Germany	28/10/2011		
Greece	18/05/2022		
Hungary	26/09/2013	09/01/2014	01/01/2016
Iceland	28/10/2011		
Ireland			
Italy	28/10/2011		
Latvia			
Liechtenstein	04/11/2011		
Lithuania	21/04/2022		
Luxembourg	22/12/2011		
Malta			
Monaco			
Montenegro			
Netherlands			
North Macedonia	09/09/2021		
Norway	12/04/2023		
Poland			
Portugal	28/10/2011	18/12/2018	01/04/2019

Republic of Moldova	20/09/2012	14/08/2014	01/01/2016	
Romania				
San Marino				
Serbia	02/10/2019			
Slovak Republic	24/10/2023			
Slovenia	06/03/2019	03/05/2022	01/09/2022	
Spain	08/10/2012	05/08/2013	01/01/2016	
Sweden				
Switzerland	28/10/2011	25/10/2018	01/02/2019	
Türkiye	29/06/2012	21/09/2017	01/01/2018	
Ukraine	28/10/2011	20/08/2012	01/01/2016	
United Kingdom				
	Non-Members of Council of Europe			
Belarus	24/06/2019	28/09/2020	01/01/2021	
Benin	29/05/2018	29/05/2018	01/09/2018	
Burkina Faso	16/02/2017	27/07/2017	01/11/2017	
Canada				
Chile				
Congo				
Côte d'Ivoire	03/07/2019	20/07/2023	01/11/2023	
Ecuador	07/05/2021			
Guinea	10/10/2012	24/09/2015	01/01/2016	
Holy See				
Israel	28/10/2011			
Japan				
Mali	29/06/2021			
Mexico				
Morocco	13/12/2012	19/04/2022	01/08/2022	
Niger	19/02/2021	10/03/2022	01/07/2022	
Russian Federation	28/10/2011	20/03/2018	01/07/2018	
Togo				
Tunisia	07/02/2024			
United States of America				
	International Organisations			
European Union				

Notes
a: Accession s: Signature without reservation as to ratification su: Succession r: Signature "ad referendum". R.: Reservations D.: Declarations, Denunciations, Derogations A.: Authorities T.: Territorial Application C.: Communication O.: Objection.
63: Since 2013 the decision to invite a non-member State to sign the treaty is valid five years as from its adoption. See the Chart on https://rm.coe.int/16806cac22
Source : Treaty Office on http://conventions.coe.int - * Disclaimer.

Appendix 2- Questionnaire for the 1st Thematic monitoring round

Please see the MEDICRIME website: https://www.coe.int/en/web/medicrime/monitoring-themes

Appendix 3- State of play of replies to the Questionnaire
(as on 18 June 2024)

States parties to the Convention	Questionnaire sent	Questionnaire Received
Albania/ Albanie	16 June 2021	
Armenia/ Arménie	16 June 2021	18 March 2024
Belarus/ Biélorussie	16 June 2021	
Belgium/ Belgique	16 June 2021	06 December 2021
Benin/ Bénin	16 June 2021	
Bosnia and Herzegovina/ Bosnie-Herzégovine	16 June 2021	14 February 2022
Burkina Faso/ Burkina Faso	16 June 2021	
Croatia/ Croatie	16 June 2021	27/11/2021
Cyprus/ Chypre	20 November 2023	30 April 2024
France/ France	16 June 2021	30/11/2021
Guinea/ Guinée	16 June 2021	
Hungary/ Hongrie	16 June 2021	29 November 2021
Ivory Coast/ Côte d'Ivoire	6 November 2023	Convention ratified:20 July 2023 Working in the implementation law
Moldova (Republic of)/ République de Moldova	16 June 2021	
Morocco/ Maroc	18 July 2013	08 February 2024
Niger/ Niger	18 July 2023	
Portugal/ Portugal	16 June 2021	13 May 2024
Russian Federation/ Federation de Russie	16 June 2021	24 December 2021
Slovenia/ Slovénie	18 July 2023	
Spain/ Espagne	16 June 2021	30 November 2021
Switzerland/ Suisse	16 June 2021	25 November 2021
Türkiye / Türkiye	16 June 2021	14 November 2023
Ukraine/ Ukraine	16 June 2021	

Appendix 4- Tables on the situation by the Parties as retards the protection of public health through the MEDICRIME Convention in times of pandemics.

Prevention and training – collection of information on policies, strategies, plans, and activities to prevent counterfeit medical products and similar crimes involving a threat to public health, in particular during times of pandemics

Table A-1 – Measures taken to provide training regarding suppliers, healthcare practitioners, police customs, and health product regulators, and specialised investigation units/bodies in the investigation of counterfeit medical products in specialised techniques (Q.1)

Belgium	a. Following the implementation of the Falsified Medicines Directive, lectures have been given to raise awareness of the possibility of falsified medicines penetrating the legal supply chain. All actors in the legal supply chain need to have a procedure in place to detect and prevent falsified medicines from entering the legal supply chain. They need to train their personnel in these procedures. b. The Federal Medicines Agency has a specialised unit to treat cases concerning falsified medicines and illegal distribution. These inspectors also give training to the police c. -Training on the job - Writing official reports for prosecutors: internal and external training - Cooperation with the Centre for Police Studies (CPS): depending on their offer
Bosnia and Herzegovina	a. no response b. In accordance with the restrictions caused by the COVID-19 virus, medical services and law enforcement agencies of Bosnia and Herzegovina during the previous period participated in trainings, mainly online via webinars, online workshops, etc., on topics within the competence of the law enforcement agencies of Bosnia and Herzegovina and topics related to criminal offenses and offenses related to counterfeiting of medical devices, active substances, excipients, additives and others. For example, par operational actions. Namely, at the initiative of the INTERPOL Lyon General Secretariat, Europol... in order to combat this type of crime. OBJECTIVES 1. Improved cooperation with other INTERPOL and member countries in the fight against illicit drug trafficking." 2. Improving cooperation at national level 2.Develop a high-impact operation against illicit trafficking in medical products in several areas, as flexible as possible for all participating countries depending on their national situation: 3 Identification and seizure of medical products (medicines and medical devices) possessed by individuals or organised criminal groups; 5. Identification of organized criminal groups involved in trafficking in medical products 6. Collection of records and documents necessary to initiate and conduct criminal proceedings against members of organized criminal groups involved in this crime 7. Analysis of intelligence to create a picture of criminal groups involved in the trafficking of medical products. c. no response
Croatia	Agency for medicinal products and medical devices organizes regular trainings about preventing and detecting falsified medical products for wholesalers and distributors, and also healthcare practitioners. This is part of Agency's Strategic plan 2022-2024, point 1.4 Clear and timely communication about the safety use of medicines with the aim of protecting

	the public health Agency will organize trainings for wholesalers and distributers (4 every year is planned) specifically for GMP issues, handling with documents in order to easilly detect falsified documents and preventing counterfeit medical products enter legal supply chain including the danger of recycled medicines from waste. For healthcare professionals in community pharmacies and hospital pharmacies, who are in the distribution chain those who order and receive medical products and dispense them to patients, expert lectures on counterfeit medicines will be held in the pharmaceutical chamber and pharmaceutical society once a year. For police and customs trainings are planned (Strategic plan 2022. – 2024.) and will be organized in the coming period in accordance with the signed Agreement on Cooperation with the Ministry of Interior. Together Medicines Agency and Customs will prepare procedure for Customs officers on the border for recognizing and handling with counterfeit medical products. Agency agreed with customs for the workshops for customs officers where Medicines Agency would share experiences and answer practical questions about examples of counterfeit medical products and falsified documents. Customs officers and SPOCs from Agency will have oportunity to meet in person and promote cooperation. Workshops will be in regional customs offices during the year, in order to increase the number of customs officers attending the workshop. In coming years plan is to include regional police officers from the units specialized for counterfeit medicines together with the customs and Agency. Customs Administration organises two rounds of training per year for customs officers with the right-holders as speakers. There is no specialised training with the representatives of the pharma sector but they are always active and participate. The Ordinance on Good Practice in the Distribution of Medicinal Products, on Issuing Authorisations for Wholesale Distribution of Medicinal Products, Registration for Brokering of Medicinal Products and on Issuing Certificates on Good Practice in Wholesale Distribution of Medicinal Products prescribes the obligation of wholesalers employees to receive permanent training on identification and avoidance of the entry of counterfeit medicine into the legal supply chain.
France	a. Good Wholesale Distribution Practices (GDMP) identify appropriate tools to support wholesale distributors in carrying out their business and to prevent the introduction of falsified medicines into the legal supply chain. Paragraph 2.4 of these GDPs provides for training that: "All personnel involved in wholesale distribution activities must be trained in the requirements of the BPDGs. He must have the appropriate skills and experience prior to the performance of his duties. Staff must receive initial and ongoing training in relation to the assigned missions, based on written procedures and a written training programme. The person in charge must also maintain the level of BPDG skills of the staff by having them undergo regular training. In addition, the training should include aspects relating to the identification of medicinal products and the prevention of the introduction of falsified medicinal products into the pharmaceutical supply chain." b. The training of staff is essential to strengthen the control of flows, guide investigations and effectively fight against offenders. On the one hand, for pharmacists in pharmacies, pharmacies for indoor use (UPI) and wholesalers, training is carried out as part of the deployment of serialization by software publishers. The National Order of Pharmacists wrote a thematic booklet "authentication of medicines" in December 2019 for the pharmaceutical chain. France MVO, the body in charge of managing the national medicines verification directory, provides various tools to fight against counterfeiting. Finally, pharmacist public health inspectors have regular training on this subject during continuing education.

	On the other hand, the Office in charge of trafficking in health products (OCLAESP) provides a training mission for law enforcement agencies dedicated to the prevention of counterfeiting of medical products, active substances, excipients, accessories, elements and materials. This training is divided into several aspects that stem directly from OCLAESP's central position on this issue, with OCLAESP being clearly identified as the most likely to provide this type of training and information. Thus, OCLAESP ensures the dissemination and updating of information, data, guides or reflex sheets aimed at alerting and informing while ensuring an efficient implementation of measures to repress these acts. More specifically, since 2019, OCLAESP has been training specialized environmental and public health investigators (EAESP), through online and face-to-face training ensuring a high level of knowledge in the field. This training is subject to regular retraining, ensuring a stable level of competence over time. This training is open to law enforcement agencies, but also to certain magistrates. Through its position of central office specialized on this theme, OCLAESP provides support to field units (Gendarmerie, Police, Customs, other services ...) on these matters, making it possible to fill the lack of knowledge of practitioners in real time. OCLAESP also conducts awareness-raising activities with public authorities and health authorities and maintains ongoing relations with the pharmaceutical industry, wholesale distributors and pharmacies in order to raise awareness of the threats of organised crime and pharmaceutical crime. OCLAESP thus participates, alongside Customs and the orders of pharmacists and doctors, in the meetings of the LEEM committee (drug companies), in the work of the G5 and exchanges regularly with the anti-counterfeiting and trademark protection groups of major pharmaceutical laboratories. The missions of the various ministerial bodies and expert agencies, defined by their respective regulations (customs, competition, consumption and fraud prevention, health) within the framework of the aforementioned training in particular allow them to act to fight against the counterfeiting of health products, in particular medical devices and in vitro diagnostic medical devices. They shall ensure that products placed on the EU market meet the requirements of Eu Regulation 2017/745 for medical devices and 2017/746 for in vitro diagnostic medical devices. The European Commission has also organised meetings of competent authorities to share information on MDs and IVDDs used in the context of the health crisis in relation to their regulatory requirements. In addition, these European regulations provide for the establishment of a unique identifier for MDs and IVDDs, which allows for even better traceability. c. In its mission to support the units, OCLAESP is regularly required to provide technical or material assistance to units or services specialized in this type of investigation. OCLAESP may thus be required to guide or advise the action of these units in the use of special investigative techniques or patrimonial and financial investigation, having developed a group dedicated to these investigative missions and perfectly able to provide advice and training in this area, a group composed of investigators specially trained in these subjects, in particular through high-level university training.
Hungary	a. These above requirements are fully granted by legislative and other measures. The National Institute of Pharmacy and Nutrition (OGYÉI) – as the responsible authority for the supervision of manufacturing and wholesale trade of medicinal products – examines through their colleagues working as Good Manufacturing Practice (GMP) and Good Distributing Practice (GDP) inspectors whether manufacturing of medicinal products meets the requirements determined by the Marketing Authorisation and is proceeded according to GMP directives. Wholesale trade of medicinal products meets

	the requirements stated in the concerning laws. However, no specific training was held in this regard. b. No dedicated training was held for the police. National Board Against Counterfeiting (hereinafter: NBAC) was established in Hungary. The full spectrum of enforcement and commercial interests are represented in NBAC, including the public administration bodies, public prosecutors, police, National Tax and Customs Administration, trademark and copyright associations, interest groups of commerce and industry, and, not least, the enterprises concerned by counterfeiting. The Government Decree on which the NBAC was set up entered into force on the 1st of February 2008. NBAC still works under the Government Decree 287/2010. (XII.16.). NBAC created an Action Plan Against Counterfeiting and it has a working group against counterfeiting of medicinal products. This Action Plan fosters the cooperation between the relevant bodies, authorities, in frame of it organising common trainings, consultations, writing information leaflets. Information booklets were made for customs about vaccines and medical devices. The purpose of these booklets was to help customs officers to recognize falsified vaccines and medical products. Although the supply chain of vaccines is centralised in EU countries and there are no private arrangements for the supply of the vaccine to corporations, companies, or individuals, the trade of falsified vaccines cannot be completely ruled out. Therefore customs needed sufficiently detailed information about vaccines. These booklets were made by OGYÉI, pharma-wholesalers and NBAC. Hungary held a 4-part training series for the staff of the National Tax and Customs Administration, with the participation of the pharmaceutical authority, the police, the Hungarian Anti-Doping Group, the Hungarian Intellectual Property Office and one member of the EUIPO, specifically focusing on the fight against counterfeit medical products. Due to the positive reception, the training series is expected to continue in the future. c. No special training was held for the police. There is no dedicated department at the police for the fight against counterfeiting medicines. Every county police criminal service is involved in this issue. There is a nominee at Directorate General for Criminal Investigation Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) (Ibolya Csako lt. colonel) who is responsible for the training of the other police forces and ensures the coordination between territorial police body and the designated unit of Europol. In general, conducting of financial investigations are mandatory for all criminal offences.
Russian Federation	In accordance with the Federal law of 27.07.2004 N 79-FZ "On the state civil service of the Russian Federation", professional development of employees of these authorities is aimed at maintaining and improving the level of qualification required for the proper performance of official duties, and includes additional professional education and other professional development activities. Professional development of a civil servant is carried out during the entire period of civil service. Roszdravnadzor regularly holds both closed conference calls and seminars for representatives of its territorial bodies on topical issues of exercising powers during the pandemic, as well as interagency meetings with representatives of interested federal regulatory authorities, and also participates in seminars for healthcare professionals. Subordinate institutions of Roszdravnadzor and the Ministry of Health of the Russian Federation (FSBI "NIC" of Roszdravnadzor, FSBI "NCESMP" of the Ministry of Health of the Russian Federation) organize educational seminars, professional development programs for healthcare professionals. During the pandemic, the training events switched to an online format, and focused on issues related to working in a pandemic, ensuring patient safety, quality control and ensuring the safety of personal protective equipment.

	The issues of countering falsification are included annually in the program of annual conferences, which have been held in a remote format since 2020: "State regulation in the sphere of circulation of medicines and medical devices - "PharmMedObrascheniye", "Healthcare and quality", "Modern approaches to the expertise and registration of medicines - REGLEK". In the conditions of large number of patients with COVID-19 in repurposed medical organizations there was a need for information support to doctors of various specialties. In April 2020, an Information Center on pharmacotherapy in patients with the new coronavirus infection COVID-19 "PharmaCOVID" was created for healthcare professionals on the basis of the Federal State Budgetary Educational Institution of Further Professional Education "Russian Medical Academy of Continuous Professional Education" of the Ministry of Healthcare of the Russian Federation (FGBOU DPO RMAPO). The Academy of Management of the Ministry of the Interior of the Russian Federation and its branch "Bolshevo", the St. Petersburg University of the Ministry of the Interior of the Russian Federation, the Ryazan branch of the Moscow University of the Ministry of the Interior of the Russian Federation named after V.Ya. Kikotya perform annually additional professional development programs for qualification improvement of managers and members of procurement commissions to meet the needs of the Ministry of the Interior of the Russian Federation. Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to combat illegal turnover of industrial products in the Russian Federation for the period up to 2025. The Strategy notes as one of the measures the development of human resources potential and knowledge of employees of federal executive authorities, executive authorities of the subjects of the Russian Federation, local self-government authorities in terms of countering illegal trafficking in industrial products.
Spain	Within the Strategic Plan 2019-2022 of the Spanish Medicines and Health Products Agency, the strategic objective number 5 is to optimise the training of the resources and capacities of the AEMPS (acronym of “Spanish Medicines and Health Products Agency”, in Spanish language Agencia Española de Medicamentos y Productos Sanitarios) and it is envisaged as a measure to adapt the training of staff to their area of competence, enhancing specialised training. With regard to the State Security and Corps Forces, cooperation with the AEMPS is envisaged in the specific, continuous and up-to-date training of officials specialising in the fight against falsified and illegal medicinal products and adulterated products within the framework of the cooperation agreement. The Ministry of Justice of Spain provides for cooperation with the Justice Administration on procedures relating to falsified medicinal products as experts and the drawing up of appropriate reports. Participation in training and awareness-raising activities for judges, magistrates and public prosecutors on the problem and risks posed by falsified medicines is also contemplated. The AEMPS therefore cooperates in the specific, continuous and up-to-date training of agents specialising in combating falsified, illegal and adulterated medicinal products within the framework of that cooperation agreement. It also works on the proper training of all actors involved and on raising citizens’ awareness and knowledge of this problem. It is also active in the development of specific continuing training activities for pharmaceutical inspectors in relation to falsified medicines. In the area of distribution entities, it provides the necessary ongoing training in the field of falsified medicinal products to staff responsible for the implementation of good practice in the distribution of medicinal products. At the level of the Ministry of Justice, it participates in training and awareness-raising activities for judges, magistrates and public prosecutors on the problem and risks posed by falsified medicines.

	Attention should also be drawn to the Council of Europe's HELP programme (European training programme on human rights for legal practitioners) which together with the European Committee on Criminal Matters has launched the 'MEDICRIME' course in Spain in collaboration with the Spanish Judicial School of the General Council of the Judiciary. The aim of this course is to expand the capabilities and skills of judges to improve the national implementation of the Council of Europe Convention on the counterfeiting of medical products and similar crimes posing a threat to public health. Within each Investigation Corps, generic training on financial investigations is also provided. As regards the Spanish Guardia Civil, the units specialising in the investigation of drug trafficking offences are the Consumer Affairs Section of the Central Operational Unit, the Criminal Analysis Group of the Criminal Police Technical Unit and the Organised Crime Teams (EDOAs as acronym is Spanish language) of the Comandances of the Guardia Civil. The latter share the investigation of drug trafficking with that of other types of crime. With regard to the strategic plans being developed, there are training days for EDOAs, which include issues related to drug trafficking offences. Similarly, the Criminal Police Technical Unit produces intelligence products for dissemination to the above-mentioned units, such as documents on specific issues (DARDO) or others where changes in modus operandi, new technologies used by criminal organisations, etc. are reported, information obtained from the operations carried out (RAID). The Head of the Criminal Police has published a Technical Instruction on trafficking in medicinal products, which is being updated on a regular basis and is a training and consultation document for the units involved in investigating these crimes.
Switzerland	a. Swissmedic (Swiss Agency for Therapeutic Products) provides a variety of targeted information, primarily on the website www.swissmedic.ch (factsheets for wholesalers, etc.). Furthermore, presentations are given to targeted groups, e.g. healthcare professionals (answer b) or law enforcement officials, or round tables are held with stakeholders or dialogues held with the industry). Besides regular training of all GMP/GDP inspectors (which also indirectly contributes to the training of responsible persons in the pharmaceutical industry), Swissmedic provides regular training to those in the distribution, wholesale and procurement programmes b. The Federal Customs Administration (FCA) has jurisdiction for the enforcement of national intellectual property legislation (trademark law, patent law, design law, indications of source, copyright law) as well as the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). Therefore, adequate training is provided to customs officers for the execution of tasks. Moreover, in the field of combating the import, export and transit of counterfeit medicines, the FCA works closely with Swissmedic, which acts as the single national contact point (SPOC). Swissmedic provides scientific and technical support to the FCA in the execution of its tasks. c. Close cooperation is ensured between Swissmedic and customs authorities to conduct targeted market surveillance campaigns (including training), and regular training of customs officers is carried out by Swissmedic. During the current pandemic, market surveillance operations were conducted by FCA and Swissmedic. These operations (Op. STOP I and STOP II, including training) were conducted under the umbrella of the World Customs Organization and were targeted against illegal medical products used for prevention and treatment of COVID-19. Furthermore, prosecution under penal law for violations of legislation on therapeutic products is one of Swissmedic's core processes (in addition to

	licensing, authorisation and market surveillance). While having these competences, the Penal Division of Swissmedic has the possibility of rapidly and easily accessing its scientific units if need be, thus enhancing the efficacy and efficiency of its procedures, particularly in complex and/or international cases. The various responsibilities in law enforcement under the Therapeutic Products Act (TPA) and the provision of smooth, efficient and effective law enforcement require a good, immediate flow of information and optimised cooperation between all actors. There is close cooperation between the Penal Division of Swissmedic and the Cantonal and Federal Prosecutor's Offices and law enforcement agencies. Swissmedic is responsible for monitoring the uniform correct application of the TPA and provides expertise on the topic to prosecutors and police officers through thematic information sharing, presentations and training.

Table A -2 – Oversight programmes to assess the frequency and effectiveness of the training provided (Art 18.1,2, and 3.a) (Q. 2)

Belgium	
Bosnia and Herzegovina	
Croatia	There are no such monitoring programs yet, but after one year of training for the police and customs, an assessment of the effectiveness of the training will be made. Effectivness of the trainig will be assesed according to the number of inquiries from customs and police officials to the regulatory agency and the number of requests for analysis or classification of seized drugs.
France	The specialized training set up by OCLAESP for field actors is sanctioned by an examination ensuring the level of competence of the practitioner thus trained and identified. This training is subject to an obligation of retraining, making it possible to ensure a stable level of competence and updated over time.
Hungary	No, there is no national programme in this regard.
Russian Federation	Most of the advanced training programs for healthcare specialists are carried out under public-private partnership programs, at the same time the HR departments evaluate the specialist's knowledge at the end of the training program, thus monitoring the effectiveness of the training provided.
Spain	
Switzerland	

Table A - 3 – Awareness-raising and training programmes for all those mentioned in Table A, above, and for those responsible for cleaning and waste disposal of medical product waste at all stages in the process to prevent the recycling of medical products (Q. 3)

Belgium	Yes. The strategy in Belgium to vaccinate the population involved the set-up of vaccination centra. A script for the operation of these centra was drawn up and specific guidelines were developed to handle the vaccines and all the waste coming from these vaccination centra. These vaccination centra were put under the supervision of a responsible pharmacist and a manager. The guidelines specified that all waste coming from the vaccines (the vials, the stickers, leaflets, packaging,..) had to be put in a secured area. Labels had to be made illegible. All waste had to be put in special containers in the secured area. Every week there was a Video conference for the responsible pharmacists of all the vaccination centra during which the potential fraud with waste was discussed and best practices were shared. According to Belgium law medicinal waste is high risk waste and specialised firms were put under contract to collect the waste from the vaccination centra.

Bosnia and Herzegovina	
Croatia	Ordinance on medical waste management and Instructions on handling with waste generated in the provision of health care, responsibilities and obligation of all parties involved are determined. According to the Ordinance, the producer of medical waste must collect medical waste separately, store in appropriate containers and temporarily store in a separate room until processing or handing over to an authorized person who has a prescribed license for medical management waste and keep records. Authorized person for collection and transport of medical waste must have a contract for the collection of collected waste with an authorized person for treatment, recovery and / or disposal of medical waste. Customs Administration did not have (in the last 5 years) cases of shipments containing medicines and medicinal products suspected to infringe IPRs of the brands from pharmaceutical industry sector and thus there were no reflections on the waste management. Management and disposal of waste medicinal products is prescribed in the Ordinance on Medical Waste Management (Official Gazette No. 50/15 and 56/19). Medical waste must be stored at the point of origin in a locked, covered, temporary warehouse separated from the main activity, where the inflow of rainwater on the waste is prevented. Containers for the collection of hazardous medical waste must be resistant to the effects of the dangerous properties of the contents, to cracking and piercing if sharp objects are involved, to aggressive chemicals and the like, and must withstand the usual handling and transport conditions such as vibrations and changes in temperature, humidity and pressure. In Croatia, pharmacies must accept old medicines and/or similar pharmaceutical waste, regardless of origin. Veterinary pharmacies and veterinary clinics must take over old veterinary drugs and/or similar pharmaceutical waste generated by providing veterinary services in households and/or farms. Recycling yards are also obliged to accept medical waste from households. Disposal of pharmaceutical, cytotoxic and cytostatic, as well as chemical and similar hazardous medical waste, is carried out in a facility authorized to dispose of hazardous waste by incineration. Additionally, through the implementation of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, most of the medicinal products that are decommissioned by intension of destruction are declared as medical waste and therefore cannot be introduced in the legal market. After the decision for destruction, products are managed and disposed as described in Ordinance on medical waste management (Official Gazette No. 50/15 and 56/19). Moreover, by the Ordinance on Good Practice in the Distribution of Medicinal Products, on Issuing Authorisations for Wholesale Distribution of Medicinal Products, Registration for Brokering of Medicinal Products and on Issuing Certificates on Good Practice in Wholesale Distribution of Medicinal Products (Official Gazette No. 83/13, 19/20, 32/21 and 146/22) the applicant for wholesale distribution authorisation is required to submit to the Agency the contract on the destruction of medicinal products declared hazardous waste. Additionally, Medicinal Products Act (Official Gazette No. 76/13, 90/14 and 100/18) states that the pharmaceutical inspectors conduct regular and extraordinary inspections regarding the distribution of medicinal products (wholesale distributors, pharmacies and specialised retail sale outlets). In the performance of the inspection, the pharmaceutical inspector has both the right and duty to declare as waste the product that is found defective and

	order its' handing over to the person authorised in accordance with the rules and regulations governing waste management. There are no awareness-raising campaigns organized for persons and entities responsible for cleaning and waste disposal regarding recycling of medical products. For healthcare professionals in community pharmacies and hospital pharmacies, that create medical product waste and also collect expired medications from patients, trainigs will be organized in the pharmaceutical chamber and pharmaceutical society. Regarding awareness-raising programmes for cleaning and disposal staff written instructions will be prepared with special reference to the possibility of diverting medicines or recycling the waste, and internal education for the staff will be conducted.
France	In addition to the answers given to question 1, paragraph 2.6 of good hospital pharmacy practice, which provides that "All members of the pharmacy staff for indoor use, whatever their qualification, shall receive initial and continuing training adapted to the tasks entrusted to them", may also be mentioned as examples". Thus, disposal personnel are sensitized on the disposal of medical product waste at all stages of the process in order to prevent the recycling of medical products for the subsequent manufacture of counterfeit medical products. The presence within OCLAESP of a technical advisor inspector in pharmacy makes it possible to ensure a link with the pharmaceutical community and to ensure the implementation of early warnings for this population. In addition, OCLAESP leads and coordinates investigations in the fields of the environment and public health. This transversal competence allows it to be solicited in matters of illegal trafficking of waste medical products at all stages of the process. It assists investigators and officials of other interested administrations in the conduct of their investigations. Its role is also to observe, analyze phenomena and centralize information. It is also involved in awareness-raising and training actions. It is in this capacity that he also participates in international operations initiated on these themes, in particular by Europol's RETROVIRUS operation.
Hungary	There is no awareness-raising and training programme for health workers and police. However, in general, the NBAC has set up a Working Group on Counterfeiting of Medicines, members of which are the authorities involved in the counterfeiting of medicines, as well as representatives of pharmaceutical wholesalers and pharmaceutical companies which may be affected by the subject. In 2015, a Cooperation Agreement was issued to determine the details of the cooperation jointly with the relevant authorities, NBAC and healthcare providers. The Act XCV of 2005 on Medicinal Products for Human Use and Amendments to Other Laws Regulating the Pharmaceutical Market (hereinafter: Act XCV of 2005) stipulates to which stakeholders and authorities quality defects and deficiencies have to be reported. Pharmacists involved in the wholesale distribution of medicinal products or the supply of medicinal products to the general public, retail suppliers of medicinal products other than pharmacies and doctors who administer medicinal products shall report suspected defects in the quality of medicinal products or batches of medicinal products without delay and inform OGYÉI immediately of any suspected falsification or deficiencies of medicinal products.
Russian Federation	The Ministry of Health of the Russian Federation regularly updates recommendations for doctors on the prevention, diagnosis and treatment of COVID-19, sending updated information to all medical institutions. These recommendations describe the issues of turnover and disposal of medical waste, and personal protective equipment: https://minzdrav.gov.ru/ministry/med_covid19

	On the portal of continuing medical and pharmaceutical education of the Ministry of Health of Russia, there are training materials for health professionals on the new coronavirus infection, including the explanation of the aforementioned methodological recommendations https://edu.rosminzdrav.ru/specialistam/covid-19/ The regulatory framework for the destruction of falsified medical products has been improved during the pandemic. The Order of the Government of the Russian Federation as of September 15, 2020, No. 1447 approved the Rules for the destruction of the seized falsified, substandard and counterfeit medicines. Aspects of improving the mechanism of legal regulation of the sphere of medical waste management are discussed at meetings of the Federation Council Committee on agrarian food policy and environmental management. The Decree of the Government of the Russian Federation "On approval of the Procedure for Withdrawal from Circulation and Destruction of Falsified Medical Devices, Substandard Medical Devices and Counterfeit Medical Devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval. Knowledge by employees of medical and pharmaceutical organizations of the relevant documents and the described rules is a licensing requirement and is included in the training and professional development programs of personnel.
Spain	
Switzerland	Swissmedic provides a variety of targeted information, primarily on its website www.swissmedic.ch (factsheets, etc.). Furthermore, with regard to waste disposal during the current pandemic, vaccination centres and the responsible supervising authorities were made aware of the Advice on the application of the Medicrime Convention in the context of counterfeit COVID-19 vaccines, with a focus on correct waste management of empty vaccine vials.

Table A- 4 - Reviews on the effectiveness of the governance and supervision of medical product waste disposal; Awareness-raising programmes on the importance of proper disposal and the risks that can arise from inadequate governance and supervision. (Q. 4)

Belgium	The vaccination centra were visited to give advice on the proper handling of the vaccines and the waste management. Rapport were made of these visits and if necessary, adaption to the way of working were made.
Bosnia and Herzegovina	Medical waste has several categories (infected medical equipment, surgical waste, etc.). There are awareness-raising programmes, but the risks that can arise due to poor management of medical waste control are mainly the lack of funds for waste management under the jurisdiction of cantonal medical centres with very few companies authorised for the subsequent disposal of medical waste.
Croatia	As regards the effectiveness reviews on governance and supervision of procurement entities, including healthcare facilities that create medical product waste, each regulatory entity conducts them as part of their duties (e.g. the pharmaceutical inspection conducts them during regular and extraordinary inspections). There are no awareness-raising programmes on the importance of proper disposal and the risks that can arise from inadequate governance and supervision yet.
France	
Hungary	There is no programme for health workers and police. In Hungary, according to the Decree no. 11/2017. (VI. 12.) EMMI “on waste management activities related to pharmaceutical waste generated during the

	supply of medicines to the public", waste pharmaceuticals can be placed in collection containers placed in pharmacies and in shops selling medicines, or handed over to professional staff if no collection container has been placed. The management of waste generated by healthcare providers is defined in the Decree no. 12/2017 (VI. 12.) EMMI. Under the Regulation, the cost of collecting pharmaceutical waste from the public is borne by manufacturers. In 2019, nearly 4,000 collection points already had collection bins, two-thirds of which were placed in pharmacies and one-third in shops. The amount of pharmaceutical waste collected exceeded 341 tonnes by 2022. The waste is disposed of in incinerators in Hungary.
Russian Federation	The methodological recommendations of the Ministry of Health of the Russian Federation for doctors on the prevention, diagnosis and treatment of COVID-19 are regularly updated. Roszdravnadzor's information letters on the recall of falsified medical products indicate the need to withdraw and destroy these products. Such letters are published on the official website of Roszdravnadzor, promptly sent to health management authorities, wholesale and retail trade organizations, and medical organizations. Thus, the maximum speed of informing all participants in the circulation of medical products is ensured and openness to consumers is formed. Medical and pharmaceutical organization's employees knowledge of the relevant documents and the described rules is a licensing requirement and is included in the training and professional development programs of personnel. In accordance with part 19 of Article 38 of Federal Law No. 323-FZ, falsified medical devices and substandard medical devices are subject to withdrawal from circulation and destruction on the basis of a decision of the owner of medical devices, a decision of the authorized federal executive authority exercising functions of control and supervision in the field of health protection, or a court decision. The rules for the destruction of withdrawn falsified medical devices, substandard medical devices and counterfeit medical devices were approved by Decree of the Government of the Russian Federation No. 1440 of September 15, 2020. In accordance with part 6 of Article 47 of Federal Law No. 61-FZ, falsified medicines, substandard medicines are subject to withdraw and subsequent destruction or export from the Russian Federation, counterfeit medicines are subject to seizure and subsequent destruction. In accordance with part 1 of Article 59 of Federal Law No. 61-FZ, substandard medicines, falsified medicines are subject to withdrawal from circulation and destruction in accordance with the procedure established by the Government of the Russian Federation. The basis for the destruction of medicines is a decision of the owner of medicines, a decision of the relevant authorized federal executive authority or a court decision. The rules for the destruction of seized falsified medicines, substandard medicines and counterfeit medicines were approved by Decree of the Government of the Russian Federation No. 1447 of September 15, 2020. The decree of the Government of the Russian Federation "On approval of the procedure for the withdrawal from circulation and destruction of counterfeit medical devices, substandard medical devices and counterfeit medical devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval. In order to intensify prosecutorial supervision over the implementation of laws in this area, the prosecutors of the Russian Federation regions were sent a corresponding information letter in September 2021.
Spain	
Switzerland	

Table A-5 - Specific preventive actions targeted at specific medical products involved in a recent pandemic (Q. 5)

Belgium	
Bosnia and Herzegovina	
Croatia	The Customs Administration has set 2 risk analysis rules concerning medicines. 1. The rule that controls medicinal products according to tariff numbers, where it is checked whether the importer has the approval of Croatian agency for medicinal products and medical devices. 2. The rule that controls according to the tariff number for the vaccine for SARS-CoV-19. Given that the regular chain of distribution of these vaccines is through direct channels from the EU, so such goods cannot come through customs, this risk analysis rule would identify any attempt to import vaccines through "irregular" channels.
France	
Hungary	During Covid-19 pandemic, both police and Operational Group for Protection against the Coronavirus Pandemic (this is a governmental body) regularly informed the public about the dangers of fake vaccines and fake PCR tests.
Russian Federation	In 2020 - 2021 Interpol channels have been used to share through the territorial divisions of the National Central Bureau of Interpol of the Ministry of the Interior of Russia the alerts to the World Health Organization competent alert authorities about cases of sale of falsified medicines for preventing, detecting or treating COVID-19 and notices of the Interpol General Secretariat with "orange corner" and "purple corner" regarding fake COVID-19 tests as well as counterfeit medicines detected on the territory of the Interpol member states. . Roszdravnadzor publishes information letters on its official website about falsified medicines and medical devices that have been withdrawn from circulation and are subject to destruction. (For more details, see question 23). Since July 1, 2020, mandatory system for monitoring the movement of medicines (Track and Trace) has been introduced in the Russian Federation - labelling of medicines with data matrix identification codes. Thus, the theft of a medicine is extremely difficult. (For more information, see question 25).
Spain	
Switzerland	

Education - This section aims at identifying measures aimed at educating civil society on good practices in avoiding the risks associated with counterfeit medical products.

Table B –1 - Strategies, policies and other measures implemented to educate the public on risks associated with counterfeit medical products, in particular, those involved in a pandemic (Art 18.3.b) (Q. 6)

Belgium	a. Information for the public: how to recognise an authorized medicine-> on the website of the FAMHP • Campaign 'Medicines through the internet : don't surf with your health'-> on the website, brochures and posters • EDQM publication 'Open minds, free minds' to be translated. Ongoing. • Short "breaking announcements" on social media (Facebook of FAMHP)
Bosnia and Herzegovina	Answers for questions (a), (b) and (c) YES, training at the level of the Ministry of Security and Ministries of Health, chambers of doctors and pharmacists, Law Enforcement Agencies including Customs, Media campaigns are carried out by the competent authorities at all levels.
Croatia	The Agency for Medicinal Products and Medical Devices continuously conducts awareness rising activities on dangers posed by counterfeit medicines and risks of buying counterfeits online. Extensive content aimed at educating public on these topics is published on the Agency's website. In addition, the Agency publishes a number of news relating to MEDICRIME convention and counterfeit medicines, including the news on Pangea operations, suspected counterfeits, as well as recommendations and guidelines from relevant bodies. These texts are in addition distributed via newsletter and are sent for publication in specialized publications for healthcare professionals. Recognising the importance of this topic, counterfeit medical products are regularly represented at the Agency's conferences. The Agency puts particular focus on providing information on these topics to media representatives, given the importance of their role in informing the general public. The Agency regularly provides responses to media inquiries and gives TV and radio statements on counterfeit medical products. When responding to media queries, the Agency always includes a comprehensive overview of this area, with highlighted key messages and data, as well as examples and details that vividly explain the need for raising public awareness on these dangers. Positive feedback is regularly obtained from media representatives as this approach increases their understanding of counterfeit medical products, while at the same time the information delivered by the Agency is easily adapted to media format, which facilitates and encourages their publication in a greater measure. These topics have been additionally recognised during the COVID-19 pandemic, whereby the Agency maintained its previously established approach. Customs Administration and Agency for Medicinal Products and Medical Devices participated at several public awareness events "Stop krivotvorinama i piratstvu" ("Stop counterfeiting and piracy"), organised by the State Intellectual Property Office where counterfeit medicines from earlier IPR infringement cases were presented (among products from all industry sectors) with an aim to present health related risks of the use of counterfeit medicines. Results of measures: Systematic media monitoring shows that a significant number of articles about counterfeit medical products and the threat of buying medicines on the internet are published in print publications, as well as on

	news portals, based on the information the Agency provides. Likewise, national TV and radio stations regularly include reports on dangers of counterfeit medical products in collaboration with the Agency. One example of media reporting can be found in the attachment.
France	It should be remembered in the first place that, today, France is not affected by the proliferation of falsified medicines because the distribution chain of the medicine in France is secure and under pharmaceutical control. The placing on the market of a medicinal product is strictly supervised and monitored by the health authorities. The pharmacist's monopoly on medicines makes it possible to ensure the impermeability of the French distribution circuit, in particular by respecting good dispensing practices. Regarding the subject of online sales, it remains strictly regulated in that it is authorized only to pharmacists holding a pharmacy (with site backing to the pharmacy), to guarantee the origin of each drug. These sites are also identified for the general public with an identical logo throughout the European Union, and subject to authorization by the Regional Health Agency (ARS). Materially, after extensive information campaigns at its launch in 2013, the public database of medicines implemented by the National Agency for the Safety of Medicines and Health Products (ANSM), in liaison with the High Authority for Health (HAS) and the National Union of Health Insurance Funds (UNCAM), under the aegis of the Ministry of Health, contains a lot of information directly accessible to the public. The Order of Pharmacists provides on its website information on the online sale of medicines as well as the list of pharmacies authorized for this activity. Finally, it is necessary to recall that French Customs collaborates closely with duty holders and develops its cooperation with other customs administrations. It works closely with all the French actors concerned, in particular within the framework of an inter-directional committee for the fight against counterfeiting, set up within the economic and financial ministries. The traditionally close dialogue with private partners in this field, through the activity of the National Anti-Counterfeiting Committee in particular, will be facilitated. Communications are made at the end of these committees, as well as within Operation PANGEA. Launched in 2008, it is intended to combat the illicit sale of medicines on the Internet and coordinated by Interpol and is organized annually around the World Customs Organization, health regulatory bodies, the national police and the private sector. The last operation was launched in 2019 and allows, since 2008, the withdrawal from circulation of more than 105 million units (tablets, ampoules, sachets, vials, etc.) and to make more than 3,000 arrests. In the context of the crisis, various communications have been sent to the general public by the authorities concerning the risks associated with counterfeit medical products. For example, the National Agency for the Safety of Medicines and Health Products has published on its website: - safety information, opinions and recommendations on medicines in the face of COVID-19 , - information for buyers, distributors and importers on the qualification of products used during the COVID-19 health crisis, - or a warning against products presented on the Internet as solutions to COVID-19, including Artemisia annua. In its anti-counterfeiting plan for 2021-2022, the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) focuses on counterfeit medicines and medical devices in times of health crisis.
Hungary	a.During Covid-19 epidemic, both police and the Operational Group for Protection against the Coronavirus Epidemic regularly informed the public about the dangers of fake vaccines and fake PCR tests. Public was also informed that the Government would provide vaccination to everyone free of charge. All vaccine manufacturers are only affiliated with the Government, individual sales of the vaccine are not possible.

	b. The Police and the National Tax and Customs Administration are involved in actions announced by Europol and Interpol. They inform the public about the results of these actions, drawing attention to the dangers of products obtained on the Internet or from other illegal sources. Action Plan Against Counterfeiting which has launched by NBAC take •action against websites, where medicines and medical devices are illegally marketed, and attaching procedural guide and methodology to these actions, •active participation in international actions by authorities, •active participation in targeted awareness-raising campaigns for consumers shopping online, •awareness-raising of the population about dangers, threats to public health deriving from falsified medicinal products. c. Several awareness-raising information are published in the news by the authorities. http://www.police.hu/hu/hirek-es-informaciok/legfrissebb-hireink/zsaru-magazin/kutatjak-az-alvakcinat https://koronavirus.gov.hu/cikkek/orfk-senki-ne-doljon-be-az-internetes-bunozok-vakcinahirdeteseinek Results of measures: Since the beginning of this current pandemic, the public is continuously informed and educated about counterfeit medical products (like face masks, medicines, and sanitizers), rational consumption of medical products, vaccination, and similar topics. Due to the unexpected pandemic situation, the education of the civil society was not pre-planned but it was coordinated by the Epidemiological Operative Coordinating Body.
Russian Federation	Decree of the Government of the Russian Federation No. 256-r of February 6, 2021, approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025. The Strategy also notes that uncontrolled cross-border turnover of industrial goods, based on the use of ways and methods of "open" international Internet trade, facilitates the penetration of counterfeit and falsified products into the markets of various countries. Among other things, the Strategy is aimed at increasing the level of intolerance of the population to the consumption of industrial products in illegal circulation by increasing consumer literacy of the population in the field of countering the circulation of counterfeit and falsified products. In order to prevent substandard and falsified medical products from reaching patients, Roszdravnadzor promptly analyzes information from WHO, Intrepol, Europol on the revealed facts of distribution of falsified, substandard or unauthorized medicines, medical devices, including products for in vitro diagnostics. In accordance with the WHO recommendations, press releases and warnings related to products for the diagnosis, prevention or treatment of coronavirus infection are posted on the official website of Roszdravnadzor. Press releases of regulatory authorities are quoted and distributed by the media. During the pandemic, the online sale of medicines was allowed in the Russian Federation. Order of Roszdravnadzor N 5527 of 29.06.2020 approved criteria for evaluating information in Internet resources that can lead to the blocking of sites and their inclusion in the register of prohibited sites. Among the criteria are: offer for retail sale of falsified, substandard, counterfeit medicines for human use; offer for the retail trade of unauthorized medicines; offer for remote retail sale of prescription drugs; offer for remote retail sale of narcotic and psychotropic medicines; etc. In accordance with the order of the President of the Russian Federation, the management of the Ministry of Health of Russia and Roszdravnadzor regularly visits the regions, visits medical organizations, communicates with staff and patients, gives interviews, covering the situation with the prevention of the purchase of counterfeit medical products or documents on vaccination.

	The issues of countering falsification are included annually in the program of annual conferences organized by Roszdravnadzor, which have been held in an online format since 2020: "State regulation in the field of circulation of medicines and medical devices - "PharmMedObrascheniye", "Medicine and quality", "Modern approaches to the expertise and registration of medicines - REGLEK". In addition, materials on countering the falsification of products are published on the official authorities websites and social networks. Since July 2021, the Division for Interaction with Civil Society Institutions and Mass Media of the Ministry of Interior of Russia in cooperation with the territorial bodies of the Ministry of Interior of Russia has been presenting in the media and in Internet the measures taken by the internal affairs authorities to counter distribution, manufacture and sale of counterfeit COVID-19 vaccination certificates, PCR-test results, medical certificates granting the right to exemption from vaccination, as well as medical certificates indicating the presence of a high amount of antibodies and other medical documents. A total of 1170 materials were published in the media and Internet, including: federal - 624, regional - 546. The official website of the Ministry of Interior of Russia posted 58 materials prepared by territorial bodies of the Ministry of Interior of Russia, including: about stopping illegal activities for sale of documents related to vaccination against COV1D-19, about detection of the Internet source where medical documents on successful vaccination were offered . Special attention is paid to showing examples of crime investigations related to the illegal sale of medicines, since 01.01.2021 more than 20 press releases on this topic have been published on the website of the Ministry of Interior of Russia. In particular, on 12.08.2021 a material was published about the employees of the Main Medicine Control Department of the Ministry of Interior of Russia and the Main Directorate of the Ministry of Interior of Russia in the Volgograd region suppressing a large sales channel of superpotent substances. Also, the information on the results of the work of the internal affairs authorities in this area was posted in the departmental media: in the newspaper "Shield and Sword", on the Internet portal "Ministry of Interior MEDIA", in the news releases of the radio station "Police Wave". In addition, materials on the suppression of illegal activities were published in the authority's official accounts in Instagram and Twitter. In order to form an effective mechanism of public control, free access of industry and patients to the information resources of Roszdravnadzor in the field of countering falsification has been provided (for more details, see question 23).
Spain	The Spanish Agency for Medicines and Health Products ("Agencia Española de Medicamentos y Productos Sanitarios" in Spanish language) together with the Ministry of Health promoted the campaign "No medicines on illegal websites. It is a fatal mistake for your health "to raise citizens' awareness of the health risks of medicines bought on illegal websites. The campaign remains available on the AEMPS website . The AEMPS website provides information on the authorised medicinal products and the conditions of use that are necessary for the medicinal products to offer the guarantees and benefits for which they were authorised. Furthermore, AEMPS has participated in Operation PANGEA XIII, aimed at the online sale of falsified and illegal medicines and medical devices and led by Interpol together with the Spanish Guardia Civil and the Autonomous Communities (Regions) . The 2020 report of the Spanish Agency for Medicines and Health Products shows that the AEMPS is part of the European project 11/2020-10/2025 on innovation in digital health, which aims to strengthen and prepare European citizens with information for active management of personal health and adherence to treatments. The aim is to improve access to and understanding

	of health-related information thus achieving safe use of medicines, risk minimisation and a better quality of life. In 2020, measures were also taken to plan the information campaign against falsified and illegal medicines and participated in the 'Medicines Safety Week' campaign organised by Uppsala Monitoring Centre. In January 2021, the International Federation of Pharmaceuticals (FIP), in collaboration with the World Health Organisation (WHO), published a curriculum guide to help trainers ensure that pharmacists are better able to prevent lower-quality or falsified medicines and medical products from reaching patients. In addition, the AEMPS provides some information on its website: I.- Information on the sale of medicinal products via websites and mobile applications. II.- Recalls the risks of buying falsified medicines for the treatment of COVID-19 via illegal websites and provides information to patients. III.- Provide the list of pharmacies registered for distance sales via the internet of medicinal products without medical prescription, which can be found on the AEMPS website, Distafarma: https://distafarma.aemps.es/farmacom/faces/inicio.xhtml For its part, the Spanish Federation of Associations of Pharmaceutical Industry (EFPIA) has called for extreme precautions to be taken when purchasing medicines or medical devices during this health crisis. No reports on the results of these information measures have been found.
Switzerland	a.Swissmedic provides a variety of targeted information (factsheets, etc.), primarily on its website (www.swissmedic.ch). Regarding the current pandemic, Swissmedic has issued specific warnings: • against purchasing non-conforming and illegal medical devices, • against purchasing illegal medicinal products which are used against COVID-19, and • against purchasing COVID-19 vaccines on a private basis. b.on promoting good purchasing conduct among the public to encourage rational consumption of medical products and avoiding procurement from sources that are not within your country's authorised supply systems; c.on developing and delivering risk awareness campaigns regarding counterfeit medical products and similar crimes. Answer 6b and 6c: Swissmedic regularly conducts public awareness campaigns (e.g. annual Operation PANGEA, and awareness campaigns within the framework of the Swiss public-private partnership STOP PIRACY), and issues regular publications regarding the health risks of purchasing drugs from illegal sources and ad hoc publications regarding specific dangerous illegal medicines. Reports on results of measures: No, there are no reports.

Table B-2 - Public policy to encourage or support the involvement of civil society (such as industries, publishers, academia, etc.) in the promotion of measures to combat, prevent, detect and respond to counterfeit medical products during a pandemic, or in a more general context (Q. 7)

Belgium	
Bosnia and Herzegovina	
Croatia	State Intellectual Property Office encourages this involvement through its activities, which include public awareness events "Stop krivotvorinama i piratstvu" ("Stop counterfeiting and piracy"), aimed at presenting health related risks of the use of counterfeit medicines.
France	Under Article L. 5312-4 of the Health Code, the National Agency for the Safety of Medicines and Health Products "sets up a specific monitoring and

	alert system aimed at avoiding, through the implementation of appropriate information measures, that medicinal products likely to present a danger to health in particular when they are suspected of being falsified [...] are not made available to patients'. To this end, it has set up on its website a reporting mechanism specifically concerning the non-compliant practices of an operator (manufacturer, distributor for example) intervening on these products or any serious threat to public health related to a health product. All civil society actors can use this device to alert on falsified products (Article R. 5312-1). The Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) dedicates a page of its website to counterfeiting (definition, competent authorities to be prevented) and a portal dedicated to counterfeits on the Internet. The Ministry of the Interior, through its services and in particular OCLAESP, and through agreements and partnerships, conducts awareness-raising actions with public authorities and health authorities. It maintains close relations with the pharmaceutical industry, wholesale distributors and pharmacies with a view to raising awareness of the threats of organised crime and pharmaceutical crime. Thus, the services of the Police and the Gendarmerie, alongside the Customs and the orders of pharmacists and doctors, participate in the meetings of the LEEM committee (the Pharmaceutical Companies), in the work of the G5 (group of eight French laboratories including SANOFI, SERVIER, IPSEN, PIERRE FABRE) and exchanges regularly with the anti-counterfeiting and trademark protection groups of the major pharmaceutical laboratories. This action has been particularly fruitful during the pandemic, allowing very rapid exchanges of information, whether in terms of information provided by partners to guide certain national or international investigations, but also towards the same partners to alert on modus operandi discovered in particular.
Hungary	NBAC was established in Hungary in which the full spectrum of enforcement and commercial interests are represented including the public administration bodies, public prosecutors, police and customs authorities, trademark and copyright associations, interest groups of commerce and industry, and, not least, the enterprises concerned by counterfeiting. NBAC held its first meeting on 3 March 2008 and was active through the pandemic too
Russian Federation	Since 2006, the Council of Public Organizations for the Protection of Patients' Rights under the Federal Service for Surveillance in Healthcare has been functioning in which public patient organizations, the medical and academic community, public foundations and organizations of sociological research are represented. Also the composition of the Council of Public Organizations for the Protection of Patients' Rights under the Ministry of Health of the Russian Federation was approved in accordance with the Order of the Ministry of Health of the Russian Federation No. 437 dated October 23, 2012 "On the Council of Public Organizations for the Protection of Patients' Rights under the Ministry of Health of the Russian Federation". During the parliamentary hearings, discussions are held on particularly significant issues of public importance, draft laws, international treaties subject to ratification and other issues, including in the field of falsification of medical products, with the involvement of officials, experts and the public. The hearings on health issues are initiated by the State Duma Committee on Health Protection. The hearings are broadcasted live at: http://duma.gov.ru/multimedia/video/stream/. Patient organizations and associations, including associations of patients with certain or rare diseases, regularly participate in the discussion of initiatives and results of the work of the Ministry of Health of Russia and Roszdravnadzor. Information about cases of falsification of medical products, especially highly specialized products, can be promptly obtained from representatives of the patient community.

	Representatives of regulatory authorities take part in professional congresses, covering, among other things, the issues of countering the falsification of medical products. The main patient organizations of Russia: the All-Russian Union of Patients, the All-Russian Public Organizations of disabled people with Multiple Sclerosis, the All-Russian Society of Hemophilia, the Interregional Public Organization "Help for patients with cystic fibrosis", the Russian Diabetic Association, the All-Russian Society of Disabled People, the Interregional public Organization "Assistance to disabled people with Gaucher disease since childhood and their families". For active participation in the promotion of measures to combat, prevent, detect and respond to falsified medical products, including during the pandemic, it is possible to award members of the public with a commendation, certificate of honor or other authority award.
Spain	
Switzerland	

Table B-3 - Is civil society actively engaged in raising public awareness of the risks arising from counterfeit medical products (Article 18. 3, b) (Article 18.3.b) (Q. 8)

Belgium	
Bosnia and Herzegovina	
Croatia	There are associations involved in raising public awareness of the risks arising from counterfeit products, including medical products. One example would be Brand owners association BOA. Since its establishment in 2009, BOA has organized several events together with the Customs Administration of the Republic of Croatia, and the Customs Administration on raising public awareness among consumers.
France	
Hungary	Please see the previous answer with regard to question 7.
Russian Federation	After the introduction of the mandatory traceability system for the transfer of medicines (Track&Trace), the functionality for medicines was added to the “Chestny ZNAK” mobile application. " Chestny ZNAK " is a national system of digital labeling and traceability of goods, which allows to check the legality of goods, including medical products, on the market: https://chestnyznak.ru/en/potrebitelyam/. Thus, the patient can independently check with the help of a smartphone the possibility of location of a concrete medicine package in circulation. Civil society is also involved through representatives in public councils under the Ministry of Health of Russia, Roszdravnadzor, patient organizations (see question 7). During the parliamentary hearings, discussions are held on particularly significant issues of public importance, draft laws, international treaties subject to ratification and other issues, including in the field of falsification of medical products, with the involvement of officials, experts and the public. The hearings on health issues are initiated by the State Duma Committee on Health Protection. The hearings are broadcasted live at: http://duma.gov.ru/multimedia/video/stream/ .
Spain	
Switzerland	

Table B – 4 - legislative provisions, strategies, plans and preventive measures have been taken to prevent the promotion, advertisement and dissemination of material, including virtual information and medicinal product offers, when they are contrary to internal laws, during a pandemic and generally (Article 8. a, and 18. 3. b) (Q. 9)

Belgium	In general the Law of the 25th of March 1964 on medicines stipulates that the advertising, promotion and selling of falsified medicinal product is a crime. A Facebook article was posted by the FAMHP regarding a counterfeit medicine that was distributed via an online shop. Cooperation with police and justice services: For several months the FAMHP could easily transfer reports about fraudulent websites to the specialized police service to block immediately the access to these websites.
Bosnia and Herzegovina	Unfortunately, no. An action plan and strategy would be required.
Croatia	MEDICINAL PRODUCTS ACT Article 183 (1) Medicinal products referred to in Article 106, paragraph 2, subparagraphs 1 and 2, of this Act may be advertised in scientific literature, at symposia and conferences and to healthcare professionals. (2) Medicinal products referred to in Article 106, paragraph 2, subparagraph 2, of this Act may be advertised to the public. (3) The advertising of medicinal products referred to in Article 106, paragraph 2, subparagraph 1, of this Act to the public shall be prohibited. (4) The prohibition contained in paragraph 3 of this Article shall not apply to public health campaigns for the promotion of vaccination, seroprophylaxis and chemoprophylaxis programmes drawn by the Minister in accordance with the Act on the Protection of the Population against Communicable Diseases. (5) The advertising of any medicinal product unauthorised in the Republic of Croatia, except at symposia and conferences and in scientific literature and provided that the procedure for granting of the marketing authorisation pursuant to this Act has been instituted and that only common name of the medicinal product is used, without any mentioning of the manufacturer, shall be prohibited. (6) Restrictions from paragraph 5 of this Article shall not apply to scientific and expert meetings held in the Republic of Croatia.
France	Preventing the promotion, advertising and dissemination of materials, including virtual information and the supply of medicinal products, when they are contrary to national law, falls in part within the tasks of the National Agency for the Safety of Medicines and Health Products, in particular through Article L. 5312-4 of the Health Code mentioned in the answer to question 7. Under Article L. 5312-1, it "may subject to special conditions, restrict or suspend [...] the advertising ... of a product or group of products referred to in Article L. 5311-1, not subject to authorisation or registration prior to its placing on the market, putting into service or use, where that product or group of products is present or is suspected of presenting, under normal conditions of use or under reasonably foreseeable conditions, a danger to human health, either is placed on the market, put into service or used in breach of the laws or regulations applicable to it. The suspension shall be imposed either for a period not exceeding one year in the event of danger or suspicion of danger, or until the product or group of products has been brought into conformity in the event of an infringement of the laws or regulations. " and " [...] prohibit such activities in the event of a serious danger or suspicion of a serious danger to human health. [...] ». More broadly, the communications from the National Agency for the Safety of Medicines and Health Products referred to in the answer to question 6 contribute to combating the spread of material contrary to domestic law, including as a pandemic. OCLAESP has established capabilities to detect promotional, advertising and dissemination activities of materials, including virtual information, using, inter

	alia, special investigative techniques such as pseudonymous investigations or cyber investigation capabilities. OCLAESP is also in regular contact with the Pharos platform, Platform for harmonization, analysis, cross-checking and referral of reports, a website created in 2009 by the French Government to report illegal online content and behavior.
Hungary	As we stated above (Question 6.) during the Covid-19 epidemic, both police and the Operational Group for Protection against the Coronavirus Epidemic regularly informed the public about the dangers of fake vaccines and fake COVID-tests. The public was also informed that the Government would provide vaccination to everyone free of charge and individual sales of the vaccine are not possible. The medicinal product offers – especially vaccines and COVID-test offers – were continuously monitored by health authorities and if necessary, proceedings have been initiated. (A private vaccination center offered a pre-booking option of vaccines from unknown sources but after a consumer protection procedure the promotion was withdrawn and the money was paid back.) During the pandemic, the Operational Group for Protection against the Coronavirus Epidemic controlled the strategies and the prevention of any unlawful dissemination of information. Since the general public was continuously informed within the above-mentioned awareness-raising campaign there are no other parallel campaigns are required currently.
Morocco	Apart from the two bodies mentioned (allusion to the (central) Service for the Fight against Crime Related to New Technologies, and its corollary the National Office for the Fight against Offences Related to New Information Technologies, under the National Brigade of the Judicial Police (BNPJ)), the DGSN has other services with prerogatives to investigate the incriminated facts, when new technologies are not involved. These are the National Office for the Fight against Economic and Financial Crime, which also comes under the BNPJ, which intervenes at the national level, the Regional Brigades of the Judicial Police of Casablanca, Marrakech, Rabat and Fez, which intervene at the regional level, and the Economic and Financial Brigades at the level of the territorial services of the Judicial Police – that intervene at the local level. In addition to the complaints and denunciations received, the facts investigated by these entities are often detected in the context of criminal intelligence work carried out directly and/or with the support of specialized operational entities in this area (Criminal Intelligence and Technical Support Brigades for Investigations) or in the context of exchanges and coordination efforts with the competent departments and private and associative health operators .
Russian Federation	Advertising of medicines, medical devices and medical services is regulated by Article 24 of Federal Law No. 38-FZ of 13.03.2006 "On Advertising". Advertising of falsified and unauthorized products is prohibited by law. In order to increase the availability of medicines, online medicines trade with a special permit was allowed in 2020. At the same time Roszdravnadzor's control over the sale of medicines via the Internet has been strengthened. Order of Roszdravnadzor N 5527 of 29.06.2020 approved criteria for blocking sites with prohibited information and putting them in the Register of prohibited sites. This measure is aimed at reducing the risk of counterfeit medical products reaching the patient. Among the criteria are: -offer for retail sale of falsified, substandard, counterfeit medicines for human use; -offer for the retail sale of unauthorized medicines; -offer for online retail sale of prescription medicines; -offer for online retail sale of narcotic and psychotropic medicines; -etc. By December 2021, by the decision of Roszdravnadzor, he Federal Service for Supervision of Communications, Information Technology, and Mass Media (Roskomnadzor) blocked more than 10 thousand sites. The Ministry of Interior of Russia organized cooperation with the prosecutor's office and territorial divisions of Roskomnadzor in restricting access to

	information which violates the law, in accordance with the Article 15.3 of the Federal Law of July 27, 2006, № 149-FZ "On Information, Information Technologies and on the protection of information ". In April 2020, Part 1.1 of Article 238.1 of the Criminal Code of the Russian Federation was introduced, according to which the manufacture, sale or import into the territory of the Russian Federation of counterfeit medicines or medical devices committed using mass media or information and telecommunications networks, including the Internet, are considered an aggravating circumstance.
Spain	Law 10/2013 of 24 July 2014 abolished the prior administrative authorisation for advertising of medicinal products for human use not subject to medical prescription, which is subsequently included in Article 80 of Royal Legislative Decree 1/2015 of 24 July 2007 approving the recast text of the Law on guarantees and rational use of medicinal products and medical devices. In view of the importance of the transmission of information on medicinal products for human use to the public, the Ministry of Health took the view that it was of particular importance that mechanisms should be put in place to control this type of advertising since, in principle, no alternative system of prior control was introduced by this legislative amendment. For this reason, an agreement was signed in October 2014 between the Ministry of Public Health and the main parties involved in this process, such as the "Association for Self-Care of Health (ANEFP in Spanish language)" and the "Association for the Self-Regulation of Commercial Communication (AUTOCONTROL in Spanish language)" which are the economic operators involved in the advertising of medicinal products for human use to the public, in order to ensure that the advertising messages issued comply with all the conditions imposed by the legal system. That Convention ceased to be in force in October 2020 and a new agreement between the parties was therefore necessary. As a result, the Resolution of 26 March 2021 of the State Secretariat for Health published the Agreement with the Association for Self-Care of Health and the Association for the Self-Regulation of Commercial Communication on Advertising Medicinal Products for Human Use addressed to the public (BOE of 7 April 2021). The purpose of the Convention is to establish the most appropriate mechanisms for the assessment of advertisements addressed to the public concerning medicinal products for human use, in order to ensure that they are produced with the necessary truth, clarity and objectivity and that all the conditions imposed by the relevant legislation are fulfilled. In this regard, the Association for the Self-Care of Health (ANEFP) undertakes to review all draft advertising messages submitted to them on a voluntary basis by pharmaceutical bodies to advertise medicinal products for human use to the public through a Technical Committee for the review of this type of advertising, and to inform pharmaceutical bodies of all the incidents noted in the review of the advertising projects submitted and studied. In turn, the Association for the Self-Regulation of Commercial Communication (AUTOCONTROL) undertakes to examine through its Technical Cabinet, and in accordance with its procedures, advertising campaigns sent by ANEFP under the 'ANEFP stamp' and those sent to it on a voluntary basis by advertisers, agencies or media in relation to advertising messages on medicinal products for human use addressed to the public. Moreover, in view of the proliferation of various websites and associated mobile applications for the sale of medicinal products, both subject to and not subject to prescription, which would be in breach of the legislation in force, the AEMPS has investigated and initiated various measures to ensure that the medicinal products reach the patient with the necessary guarantees of quality, safety and efficacy, accompanied by direct information and ensuring the pharmacist's professional intervention and direct communication with the patient, as provided for in the legislation in force .

	The AEMPS has also reported on the risks of buying falsified medicines for the treatment of COVID-19 via illegal websites . The AEMPS also has a mailbox medicamentos.falsificados@aemps.es to report cases of falsified or suspected medicinal products for human and veterinary use detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing or importing laboratories, wholesale drug distribution warehouses, and healthcare professionals. The Strategic Plan 2019-2022 of the Spanish Medicines and Health Products Agency (AEMPS) includes the tactical objective of providing full and reliable information on products to the public, healthcare professionals, industry, authorities and the media (Information Guarantee). The AEMPS is an information point for both citizens and industry in the various fields in which it has competences. It is therefore responsible for reviewing and authorising the information contained in the technical sheets and package leaflets for medicinal products. This information is made available to the public and healthcare professionals within each medicine package, but is also accessible from multiple platforms. CIMA and C IMA Vet, owned by AEMPS, stand out. Platforms other than CIMA and CIMA Vet consist of third-party information systems (pharmacies, hospitals, etc.) which reuse the information published by the AEMPS. The AEMPS is responsible for monitoring, with the cooperation of the Autonomous Communities (Regions) and the pharmaceutical services of the Government Delegations and Sub-Delegations, that there are no unauthorised, counterfeit or adulterated products on the market.
Switzerland	Swissmedic is the central contact point for reports regarding illegal advertisement and illegal offers and takes measures against any such activities contrary to national laws. Together with the national communications authority, Swissmedic has assessed all new websites that included “COVID”, “corona” or similar words in their domain name in order to uncover illegal offers or activities. Furthermore, Swissmedic conducts specific targeted monitoring of illegal virtual information and offers. In order to optimise such monitoring, tools for automated monitoring of illegal medicinal products and non-conforming medical devices are currently being evaluated. With regard to criminal law, unlawful advertising is punishable under the TPA (Article 87, para. 1, letter (b) in connection with Article 32). Pursuant to Article 32, para. 1 TPA, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (letter (a)), if it may incite an excessive, abusive or inappropriate use of medicinal products (letter (b)) or if it is for medicinal products which may not be placed on the market nationally or cantonally (letter (c)). Fines of up to CHF 50,000.00 may be imposed in case of a violation of this provision (cf. Article 87, para. 1).

Victims: identifying measures focused on the protection of victims' rights

Table C-1 - national law and policy for the protection of victims of crimes arising from the counterfeiting of medical products and similar crimes, specifically during times of a pandemic due to the increased risks arising (Q.10)

Belgium	Several initiatives can be mentioned. We refer to, amongst others: The Federal Police has within central direction Serious and Organised Crime (DJSOC), the section «i2-IRU» (Internet Investigation) that performs daily patrols on open sources (Internet) looking for websites offering counterfeit and/or non-mainstream products. Every file is communicated to the competent partner services (services of the integrated police, Customs, the Federal Agency for Medicines and Health Products (FAMHP) and/or the Federal Public Service (FPS) Economy, in function of the detected violation and/or the type of product offered). The Board of Public Prosecutors has designated the «i2-IRU» service as the central point of contact for investigations relating to (see the COL NR. 10/2020 of 2nd of April 2020 concerning CORONAVIRUS – Guidelines of the College of Prosecutors General on the fight against fake webshops and fake news sites): – online stores that sell counterfeit medicines or products related to Covid-19; – fake online stores that offer genuine/fake items in the same setting; – fake news sites (mainly or exclusively related to Covid-19) that can explicitly endanger public health. There is thus an collaboration between all the competent authorities to tackle theses websites. The FOD Economie has also developed a webpage containing all the information for victims (preventive measures such as how to recognize these website) and what to do when a person becomes a victim with a referral button to a central reporting point where the victim can report the facts. The website also refers to a film available on Youtube that explains this in a comprehensive and intelligible way. During criminal proceedings, the regular offer to all victims of crime (see in particular services for judicial victim support and victim support services of the competent authorities of the Communities) is also available to these victims. It is important to mention that during the pandemic, for all victims, the regular services of judicial victim support and victim support were/are not interrupted. Assistance and help however during the lockdowns were given by phone, mail or written information, if necessary, videoconference is also possible.
Bosnia and Herzegovina	At the level of Bosnia and Herzegovina, no special law has been promulgated for the protection of victims of criminal offences resulting from the criminal offences of counterfeiting of medical devices and similar criminal offences. The protection of victims of crime is prescribed by the Code of Criminal Procedure of Bosnia and Herzegovina and the Law on the Protection of Threatened and Vulnerable Witnesses. However, these laws do not define

	the term "victim" as defined by international law, but victims are treated through the terms "injured party" and "witness", as emphasized by international bodies. Therefore, it is planned to define the concept of victim in accordance with international standards throughout Bosnia and Herzegovina, so that victims of crime are protected in the same way, which means that they provide specific assistance and support. These activities will also take into account the provisions relating to the protection of victims in accordance with the MEDICRIME Convention. The Ministry of Justice of Bosnia and Herzegovina has established a working group to find adequate solutions that will eliminate the identified gaps and improve the applicable provisions of the Criminal Code of Bosnia and Herzegovina and the Code of Criminal Procedure of Bosnia and Herzegovina, which will be prepared by the Working Group in the form of a draft law on amendments to the applicable regulations, and, in order to harmonize criminal legislation in Bosnia and Herzegovina, initiate possible changes to criminal law at the level of the entities and the Brcko district. Within the framework of the work of this working group, the provisions of the Convention that need to be implemented in criminal legislation in Bosnia and Herzegovina will be examined.
Croatia	1) the right to access services for the support of victims of criminal offenses, 2) the right to effective psychological and other professional assistance and support from a body, organization or institution for assistance to victims of criminal offenses in accordance with the law, 3) the right to protection from intimidation and retaliation, 4) the right to protection of dignity during the examination of the victim as a witness, 5) the right to be heard without undue delay after the filing of a criminal report and for further hearings to be conducted only to the extent necessary for the purposes of criminal proceedings, 6) the right to accompany a person of trust in taking actions in which he / she participates, 7) the right to have medical procedures performed on the victim to the least extent and only if they are absolutely necessary for the purposes of criminal proceedings, 8) the right to file a motion for prosecution and a private lawsuit in accordance with the provisions of the Criminal Code, the right to participate in criminal proceedings as an injured party, the right to be informed of the rejection of a criminal report (Article 206, paragraph 3 of this Act) and the right to take over prosecution instead of the state attorney, 9) the right to be notified by the State Attorney of the actions taken regarding her application (Article 206a of this Act) and to submit a complaint to the Senior State Attorney (Article 206b of this Act), 10) the right, at her request, to be informed without undue delay of the termination of custody or pre-trial detention, the escape of the defendant and the release of a convict from serving a prison sentence, and the measures taken to protect her, 11) the right to be informed at her request of any decision terminating criminal proceedings, 12) other rights prescribed by law. (2) The victim of a criminal offense for which a prison sentence of more than five years is prescribed, if he suffers the more serious consequences of the criminal offense, shall be entitled to professional assistance of counselors at the expense of budgetary funds when submitting a property claim. (3) The victim of a criminal offense of violence committed with intent is entitled to financial compensation from the state budget in accordance with a special law. If the victim has previously obtained a property claim, its amount will be taken into account when determining the monetary compensation, and the court will do the same when awarding the property claim if the victim has previously obtained a financial compensation from the state budget.

	(4) The court, the state attorney's office, the investigator and the police shall, upon taking the first action in which they participate, inform the victim in a manner understandable to him: 1) on the rights referred to in paragraphs 1, 2 and 3 of this Article and Article 44 of this Act 2) on the rights he has as an injured party. (5) The bodies referred to in paragraph 4 of this Article shall treat the victim with consideration and ensure that the victim understands the given notification of rights. (6) The bodies referred to in paragraph 4 of this Article shall inform the victim in a manner comprehensible to him / her of the meaning of participation in the proceedings in the capacity of the injured party. The record shall include a notice given and a statement by the victim as to whether he or she wishes to participate in the proceedings as an injured party. When the public prosecutor or the court informs the victim that he can take or continue the persecution, he will also provide her with instructions on what actions he can take in order to exercise that right and for that purpose provide him with access to the file. The victim, the injured party and their attorney have the right to inspect the file. If an earlier inspection of the file would affect the testimony of the victim and the injured party, they acquire the right to inspect the file after they have been examined.
France	For victims of offences related to the counterfeiting of medical products and in general, Articles 2 and 3 of the Code of Criminal Procedure provide that any person who has personally suffered damage directly caused by an offence (crime, misdemeanour, contravention) may bring a civil action to make reparation for the damage suffered. This action may be brought before the criminal courts at the same time as the public action before the same court and before the civil courts. It is based on the principle of full compensation for damage. Victim support associations approved by the Ministry of Justice offer victims of counterfeit medical products and similar crimes and their relatives, free of charge and in complete confidentiality, guidance, information, assistance and assistance in their legal, administrative and social procedures. As part of their missions, these associations, composed of lawyers, psychologists, social workers, provide victims with moral and psychological support to avoid a risk of secondary and repeated victimization. This comprehensive and multidisciplinary care, free of charge and individual, is long-term. The offer of services is thus proposed at regular stages and adapted to the victim. Assistance may be provided before any legal proceedings, during the judicial proceedings and beyond them. Where necessary, approved victim support associations provide appropriate referral to specialized services such as social and medical-psychological services.
Hungary	Under Section 1 of Act CXXXV of 2005 on Crime Victim Support and State Compensation (hereinafter referred to as 'Victim Support Act') a person is considered a victim if he/she is an injured party of a crime (either felony or misdemeanour) committed in the territory of Hungary (as a general rule). A natural person can also be considered a victim of crime if he/she suffered injury as a direct consequence of a criminal act, in particular physical or emotional harms, mental shock or economic loss. The aim of victim support is to mitigate the social, moral and pecuniary injuries of victims whose quality of life has been endangered due to a criminal act. Therefore not only the directly affected person is considered a victim, but also his/her family member, who also has to bear the consequences and takes care of the funeral of a deceased victim. The relevant Hungarian legislation uses a general definition of the victim, however the service is personalized in every case, so that the needs of women and girls as victims are also taken into consideration. Victim Support Act provides victim assistance to all victims of crime and property

	infringements, i.e. it does not differentiate between victim groups. At the same time, victim support is offered and provided in each case tailored to the individual needs of the victims. In Hungary the Victim Support Service (hereinafter referred to as 'VSS') supports all victims of any kind of crime in general. (Thus it is considered as a generic victim support, in Hungary we only have a couple of specific support services, for example for victims of human trafficking and victims of domestic violence). In relation to Article 19 of the Convention, we note that in the context of assisting victims in asserting their rights, the victim support service shall assist the victim in the exercise of his or her fundamental rights and accessing health care, health insurance and social services, in a manner and to the extent appropriate to his or her needs.
Russian Federation	In accordance with Article 52 of the Constitution of the Russian Federation, the rights of victims of crimes are protected by the law, the state provides victims with access to justice and compensation for damage caused. In accordance with part one of Article 1 of the Criminal Procedure Code of the Russian Federation (CPC), the procedure for criminal proceedings on the territory of the Russian Federation is established by the CPC, based on the Constitution of the Russian Federation. The activities of authorities and official persons carrying out criminal prosecution are aimed at achieving of criminal proceedings, which, in accordance with paragraph 1 of part one of Article 6 of the CPC, includes, the protection of the rights and legitimate interests of persons and organizations who have been victims of crimes. This principle of criminal proceedings is valid at all stages. In addition, in the Russian Federation the system of state protection measures of the participants of criminal proceedings is established by Federal Law № 119-FZ of August 20, 2004 " State Protection of Victims, Witnesses and Other Participants of Criminal Proceedings" which determines the grounds and procedure for security measures, as well as measures of social support for these persons participating in criminal proceedings. The decision on exercising state protection is made by the court (judge), the head of the inquiry body, the head of the investigative authority or the investigator with the consent of the head of the investigative authority, who process the statement (message) about a crime or a criminal case, unless otherwise is provided by the criminal procedural legislation of the Russian Federation. The grounds for security measures are the presence of a real threat to the safety of the protected person, destruction or damage to his property in connection with his participation in criminal proceedings, which are applied by the authority that makes the decision on the exercising of state protection. Victims of crimes related to falsification of medical products and similar crimes, including periods of pandemics, if there are reasons established by the Federal Law № 119-FZ of August 20, 2004, are subject to state protection on an equal basis with victims of other types of crimes. According to paragraph 3 of Article 42 of the Code of Criminal Procedure, the victim is provided with compensation for property damage caused by the crime, as well as expenses incurred in connection with his participation in the preliminary investigation and in court, including expenses for a representative. In accordance with the Federal Law "On the procedure for reviewing appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, citizens, as well as legal entities, can apply to a state body, and their appeal is necessarily subject to consideration. Agreements and algorithms for interaction and exchange of information in the field of countering the circulation of falsified and counterfeit medicines and medical devices concluded by Roszdravnadzor with the Ministry of Interior of Russia, the Federal Customs Service of Russia, the Investigative Committee of the Russian Federation provide that information received from citizens can serve as a basis for the start of control-supervisory and investigative measures.

Spain	Victims of crime arising from the counterfeiting of medical products and similar offences are covered by the general provisions of the Statute of Victims of Crime, approved by Law 4/2015 of 27 April. Law 4/2015 of 27 April on the Status of Victims of Crime establishes the right to information of every victim (Article 3 (1)). Article 5 provides for the right to information from the first contact with the competent authorities. Article 7 specifically provides for the right to receive information about the criminal case and the status of the proceedings. Furthermore, Article 109 of the Code of Criminal Procedure provides for the provision of information on the rights of victims of crime. As regards assistance and support measures, Article 5 of the Victims' Statute provides for the right to information on the assistance and support measures available to victims, whether medical, psychological or material, and the procedure for obtaining them. Article 10 governs victims' right of access to assistance and support services provided by public administrations and to those provided by the victim assistance offices. As regards the reparation of victims, Article 5 of the Victims' Statute provides for the right of victims to receive information on the compensation to which they may be entitled and the procedure for claiming compensation for the damage suffered, as well as the possibility of access to a public compensation scheme. In addition, the Code of Criminal Procedure provides that, by bringing a civil action, injured parties may claim compensation for damage caused by the offence. The Victims' Statute also regulates the participation of victims in criminal proceedings (Article 11) and provides for measures to support and assist victims through the victim assistance services and offices. At present, unless mistakenly, there is no planning to establish a specific policy for the protection of victims of crime related to counterfeit medical products and similar offences.
Switzerland	Persons injured by counterfeit medical products have the status of victims within the meaning of the CrimPC and the VSA if their physical or psychological integrity has been directly affected. Victims within the meaning of the CrimPC can participate in criminal proceedings, whereas under the VSA, victims enjoy certain benefits such as advice and assistance, compensation and satisfaction.

Table C-2 - measures provided to protect the rights of victims at all stages of the criminal proceedings, in a manner consistent with the procedural rules of internal laws (Article 20. 1 to 4) (Q. 11)

Belgium	Yes. Victims of these facts benefices of the same rights as other victims
Bosnia and Herzegovina	The current provisions of the Code of Criminal Procedure of Bosnia and Herzegovina contain provisions that provide protection to victims and witnesses (victims) at all stages of criminal proceedings, with a special law providing special protection for threatened witnesses and witnesses at risk, as indicated in the answer to question No. 10
Croatia	According to the provisions of the Criminal Procedure Act (OG No 152/08, 76/09, 80/11, 121/11, 91/12, 143/12, 56/13, 145/13, 152/14, 70/17, 126 / 19 and 126/19), the police, the investigator, the State Attorney's Office and the court treat the victim of a criminal offense with special regard. These bodies are obliged to inform the victim and the injured party of their rights in the proceedings in accordance with this Act and to take appropriate care of their rights when taking action. The victim of a criminal offense has, in accordance with the Law: 1) the right to access services for the support of victims of criminal offenses,

	2) the right to effective psychological and other professional assistance and support from a body, organization or institution for assistance to victims of criminal offenses in accordance with the law, 3) the right to protection from intimidation and retaliation, 4) the right to protection of dignity during the examination of the victim as a witness, 5) the right to be heard without undue delay after the filing of a criminal report and for further hearings to be conducted only to the extent necessary for the purposes of criminal proceedings, 6) the right to accompany a person of trust in taking actions in which he / she participates, 7) the right to have medical procedures performed on the victim to the least extent and only if they are absolutely necessary for the purposes of criminal proceedings, 8) the right to file a motion for prosecution and a private lawsuit in accordance with the provisions of the Criminal Code, the right to participate in criminal proceedings as an injured party, the right to be informed of the rejection of a criminal report (Article 206, paragraph 3 of this Act) and the right to take over prosecution instead of the state attorney, 9) the right to be notified by the State Attorney of the actions taken regarding her application (Article 206a of this Act) and to submit a complaint to the Senior State Attorney (Article 206b of this Act), 10) the right, at her request, to be informed without undue delay of the termination of custody or pre-trial detention, the escape of the defendant and the release of a convict from serving a prison sentence, and the measures taken to protect her, 11) the right to be informed at her request of any decision terminating criminal proceedings, 12) other rights prescribed by law. (1) A victim of a criminal offense punishable by imprisonment for a term exceeding five years, if he suffers the more serious consequences of a criminal offense, shall be entitled to professional assistance of counselors at the expense of budgetary funds when submitting a property claim. (2) The victim of a criminal offense of violence committed with intent is entitled to financial compensation from the state budget in accordance with a special law. If the victim has previously obtained a property claim, its amount will be taken into account when determining the monetary compensation, and the court will do the same when awarding the property claim if the victim has previously obtained a financial compensation from the state budget. In this context, Hungary would like to point out that the state offers compensation based on 2004/80/EC Directive but it is provided by the state itself not by the perpetrator. And if the perpetrator is sentenced to a financial penalty, the sum of money have to be paid to the state, not to the victim. However, the victim may pursue his or her civil claim in criminal proceedings. In this case of course, the offender pays the victims. In criminal proceedings, a claim for damages or release of a thing or payment of a sum may be enforced as a civil claim, in cases provided for in the law, a claim for grievance award may also be enforced. In the cases provided for by law, the court shall order the civil claim to be enforced by other legal means. In this case, the victim may pursue the claim in a civil procedure separated from the criminal procedure. Article 20(3) of the Convention provides that Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings. Under Hungarian law, access to free legal aid is based on the financial situation, the financial need of the requesting person.

	(3) The court, the state attorney's office, the investigator and the police shall be obliged to inform the victim in a manner understandable to him / her when taking the first action in which he / she participates: 1) on the rights referred to in paragraphs 1, 2 and 3 of this Article and Article 44 of this Act 2) on the rights he has as an injured party. Article 206a (1) The victim and the injured party have the right to request a notification from the state attorney on the actions taken in connection with the criminal report or notification of the committed offense after the expiration of two months from the submission of the criminal report or report on the committed act. The State Attorney shall inform them of the actions taken within a reasonable time, and no later than thirty days from the receipt of the request, except when this would jeopardize the effectiveness of the proceedings. He is obliged to inform the victim and the injured party who requested the notification about the denial of the notification. (2) If the state attorney has not informed the victim or the injured party or they are not satisfied with the given notification or the actions taken, they have the right to complain to the senior state attorney. (3) The Senior State Attorney shall verify the allegations of the complaint and if he finds that the complaint is founded, he shall order the lower State Attorney to submit the requested notification to the complainant on the actions taken or to take the actions to be taken within a reasonable time. If the Senior State Attorney finds that the lower State Attorney's actions have violated the complainant's rights, he shall inform him thereof, stating exactly the rights that have been violated. (4) The victim and the injured party may request the notice of actions taken from paragraph 1 of this Article again after six months from the previously requested notice of actions taken, unless they have addressed a complaint to the senior state attorney referred to in Article 206b paragraph 2 of this Act. . Article 206b (1) The State Attorney shall be obliged to make a decision on the criminal report within six months from the day of entry of the report in the register of criminal reports and to inform the applicant thereof, stating the short reasons for that decision. (2) After the expiry of the time limit referred to in paragraph 1 of this Article or after the expiration of six months after the State Attorney acted pursuant to Article 205, paragraph 6 of this Act, the applicant, injured party and victim may file a complaint to the senior State Attorney. lead to delays in the proceedings. (3) The Senior State Attorney shall, after receiving the complaint referred to in paragraph 2 of this Article, request a statement on the allegations of the complaint without delay. (4) The Senior State Attorney shall, if he assesses that the complaint is founded, determine an appropriate deadline within which a decision on the application must be made. (5) The senior state attorney is obliged to inform the complainant about the action taken within fifteen days from the day of receipt of the complaint. (6) The complainant may repeat the complaint if the application has not been resolved within the time limit specified in paragraph 4 of this Article. Article 205 (1) The application shall be submitted to the competent state attorney in writing, orally or by other means.

	(2) If the application is submitted orally, the applicant shall be warned of the consequences of false reporting. A record shall be made of the oral application, and if the application is communicated by telephone or other telecommunication device, its electronic record shall be provided, where possible, and an official note shall be drawn up. (3) If the criminal report was filed by the victim, it shall be confirmed in writing that he / she has filed the criminal report with an indication of the basic data on the reported criminal offense. If the victim does not speak or understand the language of the competent authority, he or she will be allowed to file a criminal complaint in a language he or she understands with the help of an interpreter or other person who speaks and understands the language of the competent authority and the language used by the victim. At the request of a victim who does not speak or understand a language used by the competent authority, a written confirmation of the criminal complaint filed shall be transferred to the budget in a language that the victim understands. (4) If the report has been submitted to a court, the police or an incompetent state attorney, they shall receive the report and immediately submit it to the competent state attorney. (5) The State Attorney shall enter the criminal report in the register of criminal reports as soon as it has been filed, except in the case referred to in paragraphs 6 and 7 of this Article. (6) If the State Attorney has only received word that a criminal offense has been committed or has received a report from the victim, the State Attorney shall draw up an official note which shall be entered in the register of various criminal cases and proceed in the manner prescribed in Article 206, paragraph 4. of this Act. (7) If the criminal report does not contain information on the criminal offense, ie if the State Attorney cannot conclude from the criminal report for which criminal offense the report is filed, he shall enter it in the register of various criminal cases and shall invite the applicant to correct and supplement the criminal report. (8) If the applicant does not comply with the invitation for correction or amendment, the State Attorney shall draw up a note to that effect. The senior state attorney shall be notified thereof within eight days from the expiration of the deadline for correction or amendment of the criminal report, who may order the entry of the criminal report in the register of criminal reports. (9) The Minister in charge of justice shall prescribe the manner of keeping the register of criminal reports and various criminal cases.
France	Victims of crimes related to the counterfeiting of medical products can benefit from support throughout the criminal proceedings. Informing victims about the existence of their rights is one of the tasks of victim support offices. Located in each judicial court, these offices have the general mission "to inform victims and respond to the difficulties they are likely to encounter throughout the criminal proceedings". This information is provided by approved victim support associations. It is complementary to that given by judicial police officers pursuant to the provisions of Articles 10-2 et seq. of the Code of Criminal Procedure when the complaint is received. With regard to the services made available to victims, in addition to the victim support offices referred to above, victim assistance hotlines are provided by the approved associations within the Houses of Justice and Law (MJD), the Points of Access to Law (PAD). Victims can also find information on the website justice.fr also known as the "litigant portal". The single reception service for litigants (SAUJ), located within each judicial court, allows any victim to know precisely the progress of the criminal proceedings concerning him. The Code of Criminal Procedure also requires victims to be informed of their rights at all stages of the proceedings. Thus, Article 10-2 of the Code of Criminal Procedure requires, in particular, judicial police officers and officers to inform victims of their rights to obtain compensation for their damages and to bring a civil action. Pursuant to the

	same article, victims are also advised of their possibility of being assisted by a lawyer, or by their legal representative in the proceedings. When initiating proceedings, the public prosecutor notifies them of the action taken (Article 40-2 of the Code of Criminal Procedure). In addition, if the proceedings are dismissed by the public prosecutor, the victim may challenge this decision before the Prosecutor General of the Court of Appeal. In the context of judicial investigations, Article 80-3 of the Code of Criminal Procedure provides that the investigating magistrate must inform the victim, from the beginning of the investigation, "of the opening of proceedings, of his right to become a civil party and of the procedures for exercising this right. If the victim is a minor, the notice shall be given to his legal representatives". This notice specifies that she may become a civil party and the procedures for appointing a lawyer. In addition, during the course of the investigation, the investigating magistrate must notify the civil parties of the main procedural acts (expert reports, notice of end of information closing arguments from the public prosecutor's office, settlement order).
Hungary	Yes, the general rules have to be applied to the pandemic time as well. Section 51 of the Act XC of 2017 on the Code of Criminal Procedure (hereinafter: CCP) establishes the rules of rights and obligations of aggrieved parties during the whole criminal proceedings. The method of giving information about rights and obligations is ruled by Section 74 of CCP. In addition, Chapter XIV of CCP contains special rules for persons in need of special treatment. Please see the relevant text. Furthermore, Section 90-93 of CCP lays down the detailed rules of the specially protected witnesses. If the court declares a specially protected witness – among others – the case documents shall be handled in a confidential manner, only certain persons determined by CCP may be present at a procedural act, procedural acts requiring the participation of a specially protected witness may be carried out primarily through a requested court or delegate judge, and a defendant or defence counsel may not be present at such acts, and the presence of a specially protected witness at a procedural act may be allowed by way of means of telecommunication. Section 99 of CCP regulates the processing personal data in a confidential manner, and Section 181 of CCP ensures the possibility to provide written testimony. Victims have the right to participate and make statements in criminal proceedings. Legal assistance is available for them from the very beginning of the criminal proceedings. The victim support services are oriented by the specific needs of victims (to explore these, the authorities concerned must make individual assessment for victims). Thus, there are no specific provisions for victims of crime relating to counterfeit medical products, because the age and other circumstances of the specific victim has to be taken into consideration in all cases and the offered services are in accordance with this individual assessment. The VSS always provides every victim turning to it for support without eligibility check with all the necessary information about available health and social services. This informational service is always personalized. The victims can also receive basic legal assistance from the staff members of VSS and there is also the possibility to receive psychological and emotional assistance. If the VSS receives information on a victim from another authority or public or private body, immediately informs this person (based on his/her known needs) in written form on his/her right to invoke for services and on which type of services he/she could be entitled for. Victim support includes the services and the institution of state compensation. The following services may be provided to the victim: a) providing help for the assertion of interests, b) immediate financial assistance, c) confirming victim status, d) counseling, e) provision of shelter (safe house). Services are basically immediate forms of assistance that provided unconditionally to the victims. Victims are entitled to these services free of charge without eligibility check.

	VSS shall assist victims, in a manner and to the extent they may require through the legal process of enforcement of their fundamental rights and for having access to healthcare services, health insurance benefits and social welfare services. Moreover VSS provides basic legal advice and assistance to help victims to get remedy for the injury. The list is not exhaustive in order to ensure the enforcement of the special needs the individual victims may have. In this context, emotional support is worth highlighting. When psychological or emotional assistance is needed to recover from the trauma caused by the crime, a psychologist is also available within this service. The goal of the psychological or emotional assistance is for the victim to regain his/her emotional balance. The emotional assistance includes decreasing the tension caused by the criminal act, to create a secured emotional environment, to channel and voice the occurring tension and frustration or other negative feelings and to help accept the reality and to search for a solution and help the victim to move on. Emotional support (help from a psychologist) can be a short-term assistance but basically it is a long-term help (therapy-based treatments consisting of a series of meetings). The provided assistance is always based on the individual need of the given victim. In case of a child involved, the VSS should, after considering all the circumstances provide information to the victim on basic child-welfare services, specialist child-protection care and other forms of child-protection, the eligibility of these services, how to apply to them and the contacts to the institutions providing the services. The legal aid used to be a separate support service, but after 1st November 2015 it is a part of the assertion of interest support service, since it does not include an official decision of the VSS, which only directs the eligible victims to the Legal Aid Service. Everyone who turns to VSS is entitled to information and advice free of charge. This means, not only victims, but anybody can get advice from VSS. VSS informs the clients on: - the rights and obligations of victims in criminal proceedings, - the available forms and the conditions of victim support, - any other available benefits, allowances and opportunities to assert his/her rights, - contact details of state, local government, civil and ecclesiastic organizations involved in supporting victims of crime, and - how to avoid repeated victimization. The Ministry of Justice also runs a nationwide 24/7 telephone service, free of charge (Victim Line 06 80 225 225), where victims can get personalized information. The provisions of Act LXXX of 2003 on legal aid (hereinafter referred to as 'Legal Aid Act') provide the possibility for victims of crimes for legal aid with a reduced rate. As a general rule only a party in need is entitled to legal aid services, other victims may only be entitled to a reduced rate. The access to the proceedings is primarily provided for the victims by the institution of legal aid. Though under the Victim Support Act victims shall be provided with legal assistance by the VSS but this assistance is merely a basic counseling of a general nature. If the victim needs legal advice or drafting legal instruments in connection with the specific case, the VSS issues a certificate confirming his/her status, based on which Legal Aid Service provides the victim with access of the legal aid services with a reduced cost. Aid may be granted for extrajudicial proceedings, in civil actions and administrative proceedings, and in criminal proceedings. (These aids may only be granted if the other conditions laid down in the Legal Aid Act are met.) Legal aid providers shall give the parties legal advice or prepare submissions or other papers for them, and - if so authorized - inspect the documents of their case, and the State shall pay or advance the legal aid providers in lieu of the parties for the pertinent costs and fees in the amounts specified by law.

	Within the framework of legal aid, the State shall provide representation to the plaintiff, defendant, intervenor (third party), interested party, petitioner and respondent through an advocate in contentious and – with the exception of enforcement procedures – non-contentious civil proceedings, administrative actions, other administrative court proceedings and non-contentious administrative proceedings as provided for by law, and shall advance or bear the costs thereof on behalf of the party. In criminal proceedings, the State shall, within the framework of providing legal aid, provide the following support under the conditions set out in the Legal Aid Act: a) advancing the advocate's fee and expenses on behalf of the injured party, private prosecutor, substitute private prosecutor, private party, stakeholder and other interested party, and bearing such fees and expenses in cases provided for by law; b) advancing and bearing the fee and expenses of the mandated lawyer on behalf of the defendant. The content of the support is regulated in CCP.
Russian Federation	In accordance with part three of Article 11 of the CPC, if there is sufficient evidence that the victim, witness or other participants in criminal proceedings, as well as their relatives and partners are threatened with murder, violence, destruction or damage to their property or other dangerous unlawful acts, the court, the prosecutor, the head of the investigative authority, the investigator, the inquiry body, the head of the inquiry department, the head of the inquiry unit and the interrogator take within their competence in relation to these persons the security measures provided in part nine of Article 166, part two of Article 186, part eight Articles 193, paragraph 4 of the second part of Article 241 and the fifth part of Article 278 of the Criminal Procedure Code, as well as security measures provided by the legislation of the Russian Federation. Among the legislative acts regulating the application of security measures is the Federal Law No. 119-FZ of August 20, 2004, according to which security measures can be applied at all stages of criminal proceedings.
Spain	
Switzerland	

Table C-3 - measures provided to permit victim support and advocacy groups, NGOs and other groups to assist and support victims, with their consent, during criminal proceeding and outside of proceedings concerning offences related to counterfeiting of medical products and similar crimes involving a threat to public health (Q. 12)

Belgium	In Belgium, several services are involved in offering assistance to victims in criminal proceedings, all within their own competences. Their interventions are differentiated and complementary. To assure an overall support to victims, these services collaborate on a regular basis and coordinate their actions in a structural way to improve their way of working on a permanent and practical basis. The services of judicial victim support are state services, which depend on the three communities of Belgium. The justice assistants of these services can provide the victims and/or their relatives with specific information regarding their individual penal case, during the entire judicial procedure, from the complaint at the police to the (conditional) release of the offender. They can offer them every necessary support during this procedure (for instance : guiding a victim when given insight in the criminal file, supporting the victim when personal belongings which have been subject to investigation are handed back, supporting the victim during the proceeding before the court). They can also refer victims to other, specialized services or organizations depending on the

	needs of the victim. Victim support is implemented by the victim support services, recognized and / or subsidized by the Communities, independent of the police and judicial authorities. The general mission of these services is to provide social and psychological assistance to victims of crime and their relatives. These services provide free social support aimed at restoring the living conditions of the victim and reintegration into work life or a psychological support adapted to the needs of the victims in order to help them find a new life balance. This support can be of short time or long term, depending on the needs of the victim. The interviews are organized according to the needs and the mobility of the victims: they can be organized in a room that offers the guaranteed discretion or, if necessary, in the victim's home or another place (e.g. a hospital) and even via phone. When the victim wishes so, he/she can be accompanied by a representative/employee of the service when effectuating certain steps (e.g. doctor's visit, visit to a police station). When needed, the victim is referred to more specializedorganizations (e.g. for psychotherapeutic support). The intervention of the services of judicial victim support and the victim support services is free of charge. Court audiences are public, so NGO's and other groups can be present during the court audiences. Third party reporting in Belgian criminal proceedings is limited to certain offences (see TEH, domestic violence and child sexual abuse images). On can also refer to our legal aid system. Legal aid may take two forms: primary legal aid and secondary legal aid. Primary legal aid is granted for "practical information, legal information, an initial legal opinion or a referral to a specialist body or organization". It takes the form of free consultations, given via a rota service organized by the commissions for legal aid (Article 508/2 of the Judicial Code). These commissions are legal bodies and are organized by each legal district. They are formed as follows: 50% barristers designated by the Law Society for the district concerned, 25% representatives of public welfare assistance centers, and 25% approved legal aid organizations. Secondary legal aid is defined as aid granted to a natural person for "detailed legal advice or legal assistance within the framework of proceedings". It is organized by the legal aid offices accountable to the bar associations. Unlike primary legal aid, secondary legal aid is provided exclusively by barristers. Secondary legal has different financial thresholds which can lead to totally free legal aid or partially free legal aid. In addition to those people who have to prove the insufficiency of their resources, there is another category of people who benefit from a presumption that they do not have sufficient resources (so that they are below the thresholds). They just have to show the documents proving that they belong to the categories defined by the Royal decree. Categories : persons who receive a social integration allowance from the CPAS (public social aid); persons who receive a guaranteed income for elderly persons from the National Pensions Office; persons who receive a disabled replacement income; a detainee, asylum seeker, etc… Minors benefit from a irrebuttable presumption that they have enough resources. Therefore totally free legal aid is granted in every case. Legal assistance consists of exempting those who do not have sufficient resources to pay the cost of proceedings (not the lawyers' fees), in full or in part, from paying the relevant costs, which are consequently paid for by the State budget.
Bosnia and Herzegovina	As indicated in the answer to question number 10, there is no special law at the level of Bosnia and Herzegovina for the protection of victims only for these types of crimes.

Croatia	Ministry of Justice and Public Administration RoC: Service for Victim and Witness Support - Central body for coordination of development of victim and witness support system 1. Provision of information to victims about the release of the offender from the prison: - information about the regular or conditional release of the prisoner - provision of additional support in cooperation with other relevant organizations and institutions (police, social services, probation offices, prisons, civil society organisations) 2. Provision of information and support to victims and witnesses: - information about the rights in written form (informative letter) sent to victims and witnesses that are summoned over the mutual international legal assistance (Croatian citizens who are summoned to testify abroad and foreign witnesses summoned to testify in Croatia) - information and support provided over the phone, referral to other relevant services 3. Provision of compensation to victims: - administering professional, administrative and technical tasks for the Committee on compensation to crime victims, according to Act on monetary compensation for victims of criminal offences - the victim may exercise his/her right to compensation for the cost for medical treatment, loss of earnings up to the amount of kn 35.000,00, close blood relatives of a deceased victim is entitled to compensation for loss of statutory maintenance of up to kn 70.000,00, for funeral expenses up to the amount of kn 5.000,00 II Courts Victim and Witness Support Departments at the courts - There are 10 Victim and Witness Support Departments at the courts (County courts in Zagreb, Osijek, Sisak, Vukovar, Zadar, Split, Rijeka, Karlovac, Šibenik and Bjelovar), additional 7 Department have been established during the 1st quarter of 2024 (at 5 County courts: in Pula, Velika Gorica, Slavonski Brod, Varaždin and Dubrovnik and at 2 biggest Misdemeanour courts , Misdemeanour criminal court in Zagreb and Misdemeanour court in Split) - Support Departments provide emotional support, practical information and information about rights to victims and witnesses. They provide support from the investigation phase till the end of court procedure. They provide information for individual need assessment and recommendations regarding victims needs and protection measures and as a person of trust, provide escort to victims in court rooms while testifying - They provide support also at Municipal courts and their Misdemeanour departments (for domestic abuse). 4. Financial support to NGO's a) Programme "The Network of support and cooperation for victims and witnesses of criminal offences" that is created with the intent of providing assistance and support for victims and witnesses of criminal offences in 13 Counties in Croatia, where victim and witness support departments have not been established. b) Civil society organizations from the Network provide support to victims and witnesses of crimes and misdemeanours. They provide information on rights, emotional support, psychological and legal counselling and, as a person of trust, provide escort to competent courts and other relevant institutions in in their counties c) National Call Centre for Victims of Crime – NPC 116 006 - an anonymous and toll-free number which provides emotional support, legal and practical information to victims, witnesses and their family members. The service is available in both, English and Croatian, 24/7 5. Coordination of the National Committee for Monitoring and Development of Victim and Witness Support System

	- members of the National Committee are representatives of: Ministry of Interior (the police), Ministry of Labour, Pension System, Family and Social Policy (social welfare), Ministry of war veterans; representatives of the State Attorney's Office, The Government's Office for Human Rights; Civil society organisation's representatives and independent professionals. - National Committee delivered National strategy for Victim and Witness Support 2016-2020 and Action plan
France	Victim support associations approved by the Ministry of Justice offer victims of counterfeit medical products and similar crimes and their relatives, free of charge and in complete confidentiality, guidance, information, assistance and assistance in their legal, administrative and social procedures. As part of their missions, these associations, composed of lawyers, psychologists, social workers, provide victims with moral and psychological support to avoid a risk of secondary and repeated victimization. This comprehensive and multidisciplinary care, free of charge and individual, is long-term. The offer of services is thus proposed at regular stages and adapted to the victim. Assistance may be provided before any legal proceedings, during the judicial proceedings and beyond them. Where necessary, approved victim support associations provide appropriate referral to specialized services such as social and medical-psychological services. This assistance benefits any victim regardless of his nationality and place of residence, including even if he resides abroad.
Hungary	The general rules have to be applied to the pandemic time as well. According to Section 59-60 of CCP, to represent and protect the rights and legitimate interests, and facilitating the exercise and performance of the rights and obligations of – among others – aggrieved parties, certain people determined by CCP may participate in a criminal proceeding as an aide. Please see the relevant text. The regional victim support services, the Victim Support Centers and the Victim Support Line provide information and assistance tailored to the individual needs to victims of all crimes. VSS cooperate and maintain contact with both state bodies, non-governmental organizations and religious communities. As a result of this cooperation, in case a victim support service is unable to provide direct assistance through its services or that a victim needs a kind of service that can better be provided by another organization, the service directs the victim concerned to governmental or non-governmental organizations as well as to church best suitable to providing personalized, fast and efficient assistance. For this reason, the Ministry of Justice have concluded numerous cooperation agreements with organisations listed above. We are not aware of any non-governmental organisations that would deal with victim support in those crimes that fall into the scope of Medicrime. Through the victim support services, Hungary assists victims in asserting their rights; certifies victim status; and provides immediate financial aid.
Russian Federation	According to paragraph 8 of the second part of Article 42 of the Code of Criminal Procedure, the victim has the right to have a representative. If a legal entity is recognized as a victim, its rights are exercised by a representative (part nine of Article 42 of the CPC). The representatives of the victim, of the civil plaintiff and of the private prosecutor can be lawyers, and the representatives of the civil plaintiff, who is a legal entity, can also be other eligible persons in accordance with the CPC of the Russian Federation to represent his interests. As a representative of the victim or civil plaintiff, one of the close relatives of the victim or civil plaintiff, or another person, whose admission is requested by the victim or civil plaintiff, may be admitted (part one of Article 45 of the Code of Criminal Procedure). Representatives of the victim, civil plaintiff and private prosecutor have the same procedural rights as the persons they represent (part three of Article 45 of the CCP). Participation in the criminal case of the representative of the victim does not deprive him of the rights provided by part ten of Article 42 of the CCP.

	Patients can seek support from patient organizations and associations, for example, the All-Russian Union of Patients, the All-Russian Public Organization of Disabled People with Multiple Sclerosis, the All-Russian Society of Hemophilia, the Interregional Public Organization "Assistance to patients with Cystic Fibrosis", the Russian Diabetic Association, the All-Russian Society of Disabled People, the Interregional public Organization "Assistance to disabled people with Gaucher's disease and their families", etc. Also in Russia, the rights of victims are protected by ombudsmen, including the Plenipotentiaries under the President of the Russian Federation for human rights, for the rights of the child, for the protection of the rights of entrepreneurs, for the rights of students.
Spain	
Switzerland	

Table C-4 - civil society active engagement in providing supportive facilities for redress and recovery of victims of counterfeit medical products and similar crimes involving threats to public health (Article 19. b) (Q13)

Belgium	
Bosnia and Herzegovina	The involvement of civil society is possible through activities related to the exercise of activities registered in accordance with the laws on associations and foundations
Croatia	The Network of Support and Co-operation for Victims and Witnesses of Criminal Offences is a network of 10 civil society organizations with 1 coordinator, that is created with the intent of providing assistance and support for victims and witnesses of criminal offences in 17 Counties in Croatia. Network members participated in numerous educations and thematic lectures with the aim of improving knowledge and strengthen their capacity to provide support and assistance to victims and witnesses. All members of the Network are continuously participating in educational activities with the aim of providing the highest quality services to victims and witnesses. Coordinator of the Network, Women's Room and member organization, Victim and Witness Support Service are members of Victim Support Europe, leading European umbrella organization advocating on behalf of all victims of crime, no matter what the crime, no matter who the victim is. More information on the Network is available at https://mrezapodrskeisuradnje.com/en/o-mrezi/
France	Through a mechanism of national solidarity, article 6 of Law No. 91-647 of 10 July 1991 on legal aid provides that legal aid may be granted without means test when the applicant's situation "appears particularly worthy of interest in the light of the subject matter of the dispute or the foreseeable burdens of the trial". By means of this provision, victims of offences established pursuant to the MEDICRIME Convention are likely to have access to free legal aid. In addition, any natural person who, having become a civil party, has benefited from a final decision granting him compensation for the damage he has suffered as a result of a criminal offence, but who cannot obtain compensation pursuant to Articles 706-3 or 706-14 of the CCP, may apply for assistance in the recovery of damages and sums awarded pursuant to Articles 375 or 475-1 of the CCP. In the absence of voluntary payment of the sums due by the convicted person within two months of the day on which the conviction became final, the civil party may refer a claim for compensation to the victims' guarantee fund.
Hungary	In Hungary, the White Ring Public Benefit Association operates alongside the government victim protection system, providing assistance not only to victims of "MEDICRIME Crimes", but to all victims of crime.
Russian Federation	
Spain	
Switzerland	

Table C-5 - measures in place or planned to enable victims to report offences impacting them and to receive protection and assistance in respect of offences established in accordance with this Convention; Oversight to assess the effectiveness of such measures (Q.14)

Belgium	
Bosnia and Herzegovina	As indicated in the answer to question number 10, there is no special law at the level of Bosnia and Herzegovina for the protection of victims only for these types of crimes. However, the reporting of a criminal offence is made in accordance with the laws of criminal procedure. The Code of Criminal Procedure of Bosnia and Herzegovina prescribes the following: A citizen has the right to report the commission of a criminal offence. Every person is obliged to report the commission of a criminal offence when failure to report the criminal offence constitutes a criminal offence (Article 214). The request shall be submitted to the Prosecutor, in writing or orally. If the application is made orally, the person submitting the application will be notified of the consequences of misrepresentation. A recording will be made of the oral application, and if the application is communicated by telephone, an official note will be made. If the request is submitted to the Court, an authorized official or another court or prosecutor in Bosnia and Herzegovina, they will receive the request and immediately submit it to the Prosecutor (Article 215).
Croatia	The Ministry of Justice and Administration has a leading role in the institutionalization of the victim and witness support system within the judiciary, and coordinates the victim and witness support system in the Republic of Croatia. Among other measures in place, it is worth highlighting the National Call Center, which provides a free service: inform victims of their rights and ways of their realization, emotional support, and refer victims to other institutions and organizations that can provide them with professional assistance. National Call Center for Victims of Crime and Misdemeanors 116 006 is available for the entire territory of the Republic of Croatia every working day from 08:00 to 20:00. More information on the Centre is available at https://pzs.hr/en/national-call-center-for-victims-of-crime/
France	Reference should be made to the answer to question 11 above Article 15-3 of the Code of Criminal Procedure also requires judicial police officers and officers to receive complaints from victims of crime and to give them a receipt informing them of the limitation periods and their right to become a civil party to interrupt the limitation period.
Hungary	The Victim Support Line (06 80 225 225), which is available free of charge 24 hours a day, is run by the Ministry of Justice to ensure that citizens who are victims can obtain information outside office hours. By calling the Victim Support Line, victims can obtain legal information and advice on their rights and obligations in criminal proceedings, the types of assistance available, the conditions and procedures for applying for assistance, and the best way to solve the problem they are facing.
Russian Federation	In accordance with the second part of Article 21 of the CPC, in each case of detection of signs of a crime, the prosecutor, investigator, body of inquiry and interrogating officer take measures provided for by the CPC to establish the event of a crime, to expose the person or persons guilty of committing the crime. The reasons for initiating a criminal case are, among other things, a statement of a crime (paragraph 1 of part one of Article 140 of the CCP), as well as a message about a committed or impending crime received from other sources (paragraph 3 of part one of Article 140 of the CCP). The interrogator,

	the inquiry body, the investigator, the head of the investigative authority are obliged to accept, check the report of any committed or impending crime and, within the competence established by the Criminal Procedure Code, make a decision on it (part one of Article 144 of the Criminal Procedure Code). According to the information about the crime spread in the mass media, the inquiry is carried out by the inquiry authority on behalf of the prosecutor, and also by the investigator within the instructions of the head of the investigative authority (part two of Article 144 of the Criminal Procedure Code). Part four of Article 7 of the Code of Criminal Procedure directly states that the decisions of the investigator, the inquiry body, the head of the inquiry body, the head of the unit of inquiry, the interrogator must be lawful, reasonable and motivated. Compliance with this requirement is guaranteed by the provisions of the Code of Criminal Procedure, in particular those regulating issues of judicial and authority control, as well as prosecutorial supervision over the procedural activities of the authorities of inquiry and preliminary investigation authorities (Article 125, paragraph 2 of the first part of Article 39, paragraph 1 of the second part of Article 37, paragraph 1 of the third part of Article 40.1, paragraph 3 of the first part of Article 40.2), a special procedure for extending the deadlines for checking a report about crime (part three of Article 144 of the CCP), the requirement to inform the applicant about the decision made based on the results of the verification of the report about crime (part two of Article 145, parts third and fourth articles 148 of the CPC). In order to improve legislation in the field of protection of the rights of victims, a working group has been formed on behalf of the President of the Russian Federation to prepare proposals for amendments to the Criminal Procedure Code of the Russian Federation in terms of optimizing the stage of initiation of criminal proceedings. This work is under the control of the Commissioner for Human Rights in the Russian Federation and is carried out with the participation of the Prosecutor General's Office, scientific institutions and the Victims of Crime Support Fund (part of the European Victim Support Association – Victim Support Europe). Citizens may appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact by phone hotline, or send a complaint through the Unified Portal of Public Services. Such appeals must be considered in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ. Compliance with the requirements of this Federal Law is monitored by the Prosecutor's Office. Information about offenses in the presence of signs of a criminal offense is transmitted accordingly to investigative or law enforcement authorities.
Spain	
Switzerland	

Cooperation and Information Exchange: the ability and extent to which authorities/bodies may cooperate between them and exchange information in order to facilitate effective investigation.

Table D-1 - measures that your country has taken or plans to take to adopt a national strategy and/or formal action plan on cooperation and information exchange between authorities/bodies to combat counterfeiting of medical products and similar crimes and whether they specifically make provision for pandemic situations (Article 17.1) (Q 15)

Belgium	The Pharma-& Food Crime Platform : this platform ensures national exchange of information and cooperation between health authorities, Customs and the police. The Federal Agency for Medicines and Health Products has appointed a focal point for WHO, a SPOC for Medicrime and a SPOC for WGEO. These SPOCs ensure the exchange of information internationally. The cooperation with customs services, but also with the FPS Economy (mouth masks) and FPS Public Health was expanded and the communication between the various authorities was optimized during the pandemic.
Bosnia and Herzegovina	In accordance with the signed agreement on cooperation between the competent agencies of Bosnia and Herzegovina and the action plan adopted by the Council of Ministries of Bosnia and Herzegovina, activities have been undertaken with a view to the establishment of the Medicrime Convention. In addition, there is an entity-level strategy for waste management under the Basel Convention for non-compliance with waste management.
Croatia	Cooperation and information sharing between public authorities/bodies is mandatory pursuant the Article 8(1) of the Law on the state administration system. 29th March 2021. Agency for medicinal products and medical devices signed a Cooperation agreement in the field of the fight against falsified medicines and medical devices with Ministry of Internal Affairs. In this agreement information exchange procedures are described.
France	In terms of public health, all the French authorities in charge of these issues have initiated exchanges of information by collaborating directly (ANSM, ANSES (ANMV), National Order of Pharmacists, Orders of Physicians, BNEVP, DIRRECTE, DGCCRF, AFLD, CNAMTS, etc.). Where an authority with the power to monitor health matters finds or detects a suspicion of damage to public health, it shall inform the judicial authority thereof by means of Article 40. This information then leads to the initiation of public action by carrying out investigations by the police forces. Since the outbreak of the pandemic, OCLAESP has largely anticipated the various threats likely to arise from this situation, particularly in view of foreseeable shortages, drugs presented as remedies or vaccines marketed. This anticipation, in connection with cooperation actions with the civilian environment in particular, has made it possible to guide its actions to prevent and detect criminal acts related to this issue. This action has prevented or ended many initiatives by criminal organizations seeking to take advantage of this pandemic situation. Within the framework of international cooperation, OCLAESP coordinated with Europol, Interpol, the European Union Intellectual Property Office (EUIPO), the Pharmaceutical Security Institute (PSI) and the European Anti-Fraud Office (OLAF). in order to exchange the information collected very quickly and to identify emerging threats identified internationally. This

	information has made it possible to feed even more the members of the forces of law and order, but also its partners in civil society.
Hungary	There is no national strategy. Not especially in the context of pandemics but even before that, continuous and effective cooperation has been developed between health authority, National Tax and Customs Administration and the police since the implementation of the Medicrime Convention in Hungary. Recently, the cooperation has become more frequent not only between the above authorities, but also between the pharmaceutical wholesalers and pharmaceutical manufacturers concerned. Cooperation is based on the legal mandates, but also includes informal contacts between the relevant authorities. Police has set up an online anti-drugs and anti-counterfeiting task force with representatives of the relevant authorities. This working group will develop recommendations and methodological guidelines in this area.
Russian Federation	Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025. The Strategy is designed to ensure coordinated interaction of interested state authorities, market participants and consumers at the federal, regional and local levels, including through the use of interstate mechanisms to counter the illegal import, manufacture and turnover of industrial products on the territory of the Russian Federation. Among the priorities of the Strategy are: -increasing the level of coordination of public authorities in the implementation of control and supervisory activities, -increasing the control and interaction of the authorities of the Russian Federation with the authorities of the member states of the Eurasian Economic Union in the field of movement of counterfeit and falsified products across the customs border of the Eurasian Economic Union. The strategy of medicines supply to the population of the Russian Federation for the period up to 2025, approved by the order of the Ministry of Health of Russia dated February 13, 2013 N 66, providing for the establishing a system of effective cooperation of interested federal executive authorities, executive authorities of the constituent entities of the Russian Federation and public organizations will achieve coordinated actions in the implementation of the Strategy's activities. One of the prospects for the implementation of the Strategy is: “Through the implementation of measures included in the Strategy for the development of the state system for ensuring and controlling the quality, efficacy and safety of medicines for human use it is planned to significantly reduce the existing risks associated with the circulation of falsified and substandard products, as well as with adverse events of medicines for human use”.
Spain	In relation to the coordination of investigations between different police forces, all operations, including those related to pandemic related crimes, are recorded in the Spanish Guardia Civil databases, which are crossed through the Intelligence Centre against Terrorism and Organised Crime (CITCO) with the databases of other police or customs forces. If there are overlaps between the entities under investigation, this body informs the units involved so that they can be coordinated. As regards the pandemic, at international level, INTERPOL has included in its operation PANGEA on internet drug trafficking, medicines and COVID-19 related crimes. Europol has also included this type of crime through Operation SHIELD on drug trafficking. As well as actively participating in PANGEA and SHIELD, when the pandemic began, a Service Order was drawn up to coordinate and enhance the investigation of offences linked to it, among all units.
Switzerland	Within the national network of authorities engaged in enforcement against counterfeit medical products and similar crimes, a scheme on cooperation and information exchange has been adopted at their annual Medicrime

	Meeting. This scheme is promoted, reviewed and adapted annually by the national network. This scheme is valid for non-pandemic and pandemic situations. Additionally, Fedpol has established a distribution list for all information related to COVID-19 that comes through police networks. The national contact point according to Article 22.2 is included in this distribution list. So far, Switzerland, i.e. the authorities with regard to market supervision of therapeutic products, have not adopted any specific measures for pandemic situations. Swissmedic, Swiss Agency for Therapeutic Products, is currently working on an enforcement-strategy for the new strategic period (2023-2026).

Table D-2 – a. Implementation of the national strategy/action plan supported and underpinned by enabling legislation (Articles 17.1, 17.3, 21.1, 21.2); b. Memorandum of Understandings and Data Sharing Agreements and c. effectiveness thereof (Q16)

Belgium	a. Yes. The law of the 25th of March 1964 list the competences of the inspectors of the FAMHP and the exchange of information is listed.
Bosnia and Herzegovina	
Croatia	a. Cooperation and information sharing between public authorities/bodies is mandatory pursuant the Article 8(1) of the Law on the state administration system. b. At national level, in combating counterfeit medicinal products and medical devices, HALMED shares information with Ministry of Internal Affairs (MOU signed on 29 March 2021) and Ministry of Finance, Customs Administration, based on agreements. At international level, HALMED exchanges information within several networks, as described in reply to Question 21. c. Based on the Cooperation agreement in the field of the fight against falsified medicines and medical devices HALMED and Ministry of Internal Affairs will hold regular meetings at least twice a year for the purpose of informing and planning further activities.
France	The Ministry of the Interior, through the Central Directorate of the Judicial Police, has set up, in parallel with the establishment of central offices, an International Relations Division (DRI), one of the fundamental tasks of which is to coordinate operational police cooperation.
Hungary	There is a co-operation agreement between the police and the National Tax and Customs Administration, but it is not limited to the fight against counterfeiting of medicines. It generally applies to all criminal offenses. As a general rule, criminal proceedings concerning the offence of counterfeiting of medicinal products are conducted by the police in Hungary. Therefore, in these cases the police has the leading role in the investigation phase of the criminal proceeding. There is a Data Sharing Agreement between the National Tax and Customs Administration (NAV) and the National Institute of Pharmacy and Nutrition (OGYÉI) for better control of the import and export of active substances. It was adopted because the VAT exemption for the importation of goods into the EU not exceeding EUR 22 has been removed from the beginning of July 2021 and not specifically because of the COVID-19 pandemic. As all goods imported into the EU are subject to VAT more small packages containing active substances will come into the sight of the customs.
Morocco	(This should) take into account the good practices of the Police in Morocco, which sends official alerts to all the authorities and bodies concerned, in particular the Ministry of Health and other law enforcement services, including Customs, about counterfeit medicines and medical devices that its (police) services seize in the context of criminal investigations or that it learns of abroad in the context of criminal investigations international cooperation, in particular within Interpol, the Council of Arab Ministers of the Interior and other regional police cooperation groups.
Russian Federation	The interaction of the Ministry of Interior of Russia with Roszdravnadzor is carried out within the framework of the Agreement dated July 31, 2015 № C2 / 15/1/6054 "On the procedure for interaction in terms of counteracting the circulation of falsified, counterfeit, substandard and unauthorized medicines and medical devices." The Ministry of Interior of Russia collectively with the Federal Security Service of Russian, Federal Customs Service of Russia and Roszdravnadzor annually conduct the international police operation "Pangea", aimed at combating crimes in the field of illegal circulation of medicines and medical devices. The coordinator of the event on the territory of the Russian

	Federation is the National Central Bureau of Interpol of the Ministry of Interior of Russia. Interdepartmental electronic interaction has been organized between the Federal Customs Service of Russia and the Ministry of Health of Russia, within the framework of which the customs authorities, when performing customs operations, receive information about the permits contained in the information resources of the Ministry of Health of the Russian Federation in automatic mode, close to real time. The Federal Customs Service of Russia, within the framework of the "Agreement on Interaction between the Federal Service for Surveillance in Healthcare and the Federal Customs Service, when providing and receiving information" dated September 10, 2013, sends to Roszdravnadzor, at its request, data on cases of administrative offenses relating to the circulation of goods, the surveillance of which relates to the established sphere of Roszdravnadzor. These agreements describe the procedure for exchanging information between authorities, the timing of its transmission, the timing of expertise (if necessary) and the provision of expert opinions. Roszdravnadzor sends information about the decisions taken on the introduction of Internet resources offering counterfeit products for sale to Roskomnadzor in accordance with Roszdravnadzor's Order No. 5527 of 29/06/2020 (see question 6) and the Decree of the Government of the Russian Federation No. 1101 of 26/10/2012 describing the operation of the Unified Register of Domain Names, indexes of pages of sites containing information which distribution is prohibited in the Russian Federation. Also, within the framework of memorandums of understanding signed between Roszdravnadzor and regulators of foreign states that have not ratified the Medicrime Convention, for example Kazakhstan, Serbia, China, India, Cuba, Brazil, Argentina, Iran, etc., information exchange is carried out on the quality, efficacy and safety of medicines and medical devices, including information on the detection of falsified products.
Spain	
Switzerland	

Table D-3 - which authority has the lead in cooperation and which participates in the operation of the plans and what oversight exists on the operation of the plans (Q17)

Belgium	Depends on the case
Bosnia and Herzegovina	
Croatia	Regarding the cooperation arrangements, lead roles lie within the Ministry of Internal Affairs or Customs Administration of the Ministry of Finance. Both the Ministry of Internal Affairs and Customs act as enforcement bodies, whilst HALMED gives support in gathering information on counterfeits, cooperates in analysis and quality control of suspected products and shares information on medical products.
France	
Hungary	Please see the previous answer with regard to question 16
Russian Federation	Roszdravnadzor is the federal executive authority that performs the function of control and supervision in the field of healthcare. In addition to the above, Roszdravnadzor forms a list of foreign medicines to which the risk profile is applied by the customs authorities when importing medicines into the territory of the Russian Federation. Roszdravnadzor, having a laboratory base for quality control of medicines and medical devices, analyzes samples of allegedly falsified or counterfeit products received from the Ministry of Interior of Russia.
Spain	

Switzerland	

Table D-4 – Involvement in cooperation arrangements with civil society, with industry or service providers (such as financial and money transfer services, e-commerce, social media platforms providers, logistics – including postal and delivery services, etc.) (Q18)

Belgium	With industry : RAS, was set up before the pandemic With postal services and logistic firms : putting in quarantine of suspect parcels. Was set up before the pandemic. Social media: Contacts were established through which reports of infringements can be easily passed on with a good follow-up
Bosnia and Herzegovina	
Croatia	National contact point interact with industry during investigation for necessary information about counterfeit medical product. Only producer have all information of the product, if it is original or not. Internet service providers are contacted by the police forces during investigation (cyber.crime@mup.hr) as they have power to shut the illegal Internet pharmacies.
France	With a view to optimizing traffic detection and improving intelligence cross-checking capabilities, initiatives are being undertaken with the private sector. Thus, an agreement has been set up by OCLAESP with the G5 which brings together eight French laboratories including Ipsen, Sanofi, Servier and Pierre Fabre. The private sector faced with problems of falsification of its production has developed devices for identifying illicit sites of sale on the Internet which constitute important resources for detecting trafficking
Hungary	A cooperation agreement exists between the police and Magyar Posta Zrt. (Hungarian Mail). Although there is no formal cooperation agreement with the other parcel delivery services operating in Hungary, informal cooperation with these service providers exists and proves to be effective, with the result of the seizure of large quantities of counterfeit medicines and anabolic steroids in several cases.
Russian Federation	In addition to the previously mentioned patient organizations, Roszdravnadzor actively interacts with specialized associations from the industry: the Association of Russian Pharmaceutical Manufacturers (ARPM), the Association of International Pharmaceutical Manufacturers (AIPM), the National Association of Manufacturers of Pharmaceutical Products and Medical Devices "APF", the Russian Association of Pharmacy Networks (RAPN), the Association of Pharmaceutical Manufacturers of the EAEU.
Spain	
Switzerland	

Table D-5 - Details on the membership or arrangements with bodies/groups dedicated to combating counterfeit medical products and similar crimes, whether investigative or advisory in nature (Q19)

Belgium	• The Pharma-& Food Crime Platform : this platform ensures national exchange of information and cooperation between health authorities, Customs and the police. They deal with cases on falsified medicines and food fraud. • Permanent Forum On International Pharmaceutical Crime (PFIPC) : this group is dedicated to the combat of falsified medicines and does this by exchange of information on an international level and stimulating mutual cooperation.

	• Member State Mechanism on substandard and falsified medical products (MSMSFM) of the WHO : this group has different working groups which provide advice to protect legal distribution chains, prevent and detect falsified medicines and facilitate access to good quality medicines. • Working group of Enforcement Officers (WGEO) of the HMA : this group promotes cooperation and the sharing of information concerning falsified medicines, identifies emerging threats and provides training. • Committee of experts on minimising public health risks posed by falsification of medical products and similar crimes (CD-P-PH/CMED) : this group is dedicated to falsified medical products by looking into threats to public health and sharing of best practices by providing training and publications
Bosnia and Herzegovina	
Croatia	Representatives of national authorities/bodies are point of contacts for the international exchange of information within the WGEO and EDQM SPOC network, as well as the WHO Global Focal Point Network for substandard and falsified (SF) medical products. Furthermore, on national level HALMED, Ministry of Internal Affairs and Customs Administration of the Ministry of Finance are dedicated to combating counterfeit medicinal products and medical devices. Except HALMED, none of the mentioned national authorities/bodies are solely dedicated to combating counterfeit medical products and similar crimes involving threats to public health.
France	An interministerial structure created by Decree No. 2004-612 of 24 June 2004, subordinate to the sub-directorate of the judicial police, the Central Office for the Fight against Environmental And Public Health Offences (OCLAESP), located in Arcueil (94), is a judicial police service with national jurisdiction. To this end, it leads and coordinates investigations carried out in the fields of the environment and public health. It assists investigators and officials of other interested administrations in the conduct of their investigations. Its role is also to observe, analyze phenomena and centralize information. It is also involved in awareness-raising and training actions. At the international level and in its field of competence, OCLAESP is positioned as a French referent for foreign law enforcement institutions and services. It is the extension of the National Central Bureau France (Interpol) for its field of competence and correspondent of Europol and Eurojust. He is also a member of various networks and working groups. Faced with these new challenges, OCLAESP underwent a reorganization in 2017 and then in 2020 to acquire a renewed competence in strategic analysis and animation of networks allowing the detection and analysis of emerging transnational phenomena, the coordination of regional actions, international positioning, in particular within EUROPOL, in terms of the environment and public health. To fulfill its missions, OCLAESP has one hundred and five gendarmes and police officers, supported by three technical advisers from the ministries in charge of sports, health and the environment. All these personnel are divided between a "Command" cell and two divisions:

	• The Command Cell consists of the head of OCLAESP, a second-in-command, his two deputies, one for European affairs and international cooperation, and three technical advisers. • The Investigations Division brings together the staff in charge of the animation, coordination and conduct of judicial investigations. In order to respond as best as possible to all requests and, in particular, to a rapid development of structured crime in its field of competence, this entity is structured around 8 detachments in metropolitan France and overseas which have investigators experienced in new investigative techniques and in charge of investigations relating to all types of illicit trafficking (waste, plant protection products, health products, but also protected species), issues related to OCLAESP's traditional competences (asbestos, major pollution of physical environments, medical or paramedical deviance, bioterrorism, health and/or food safety, etc.). The central level also has a "Financial and Digital Economic Crime Group" armed with specialists in criminal analysis and reconciliation, cyber technology, and economic crime (an essential skill in the context of the seizure of criminal assets). • The mission of the Strategy and Analysis Division is to collect and analyze operational and strategic intelligence for the detection and analysis of emerging transnational phenomena, the coordination of regional actions, and international positioning in environmental and public health matters. It advises the forces of the Ministry of the Interior as well as certain services of partner ministries. Finally, it leads training actions and institutional relations with foreign actors. This division consists of three groups: The "International Relations Group" relays, at European and international level, the action of OCLAESP in close collaboration with the relevant services of the Directorate of International Cooperation (DCI) and the Central Directorate of the Judicial Police (DCPJ). Various channels of international cooperation are thus exploited, allowing OCLAESP to be clearly identified by its international partners, particularly at European level. It is thus the OCLAESP contact point for Europol, Interpol and the network of the Internal Security Service through the Central International Security Directorate. The "Groupe Animation Prospective", a single point of entry, receives all requests from OCLAESP, provides support to territorial units in a graduated response format (telephone and documentary support, technical support and operational reinforcement), maintains an expanded and multidisciplinary network of private and public partners, ensures legal monitoring and raises awareness among all stakeholders of public health and environmental problems. in particular emerging phenomena. Last but not least, this group is responsible for evaluating the files in order to provide the most appropriate response to problems as diverse as they are complex. The "Groupe Appui Intelligence" collects and exploits criminal intelligence, in particular through investigators specializing in open source research. This group also deals with the management of human sources of intelligence and the implementation of special investigative techniques.
Hungary	Continuous and effective cooperation has been developed between health authority, National Tax and Customs Administration and the police since the implementation of the Medicrime Convention in Hungary. Recently, the cooperation has become more frequent not only between the above authorities, but also between the pharmaceutical wholesalers and pharmaceutical manufacturers concerned. Cooperation is based on the legal mandates, but also includes informal contacts between the relevant authorities. There is a MoU between Police and Hungarian AntiDoping Group from 2016, and the cooperation is very effective. Furthermore, as was mentioned above, the full spectrum of enforcement and commercial interests are represented in NBAC: • The National Institute of Pharmacy and Nutrition,

	• National Tax and Customs Administration, • National Food Chain Safety Office, • police cooperate to prevent counterfeiting. The cooperation is continuous and covers the import/export of active substances and end-products, online marketing of medical products, illegal trading of medical products, etc.
Russian Federation	
Spain	
Switzerland	

Table D-6 - Does the national strategy/action plan on counterfeit medical products stipulate or facilitate the establishment of a point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities? Is there any oversight of the effectiveness of this process? (Q20)

Belgium	The Federal Agency for Medicines and Health Products has appointed a focal point for WHO, a SPOC for Medicrime and a SPOC for WGEO. These SPOCs ensure the exchange of information internationally
Bosnia and Herzegovina	
Croatia	Yes, agreements specify the point of contact for receiving and sending alerts on suspect or confirmed counterfeit medical products between authorities/bodies. Currently, it is only specified in Cooperation agreement in the field of the fight against falsified medicines and medical devices between HALMED and Ministry of Internal Affairs that the effectiveness will be discussed on regular meetings.
France	
Hungary	There is no national strategy but OGYÉI is participating in the Single Points of Contact (SPOC) Network of EDQM, WHO, and HMA-WGEO (Working Group of Enforcement Officers) with delegated colleagues. In Hungary both the Police and OGYÉI are members of WGEO.
Russian Federation	Decree of the Government of the Russian Federation No. 256-r of February 6, 2021 approved a Strategy to counteract the illegal turnover of industrial products in the Russian Federation for the period up to 2025. Among the principles of the formation and implementation of measures in the field of combating illegal trafficking of industrial products in the Russian Federation are: coordination of efforts of federal executive authorities, executive authorities of constituent entities of the Russian Federation, local self-government bodies, bona fide manufacturers and sellers, citizens (consumers), organizations representing their interests to combat illegal trafficking of industrial products; improvement of the current mechanism of interaction of state authorities on combating illegal trafficking of industrial products; introduction of control indicators of the effectiveness of the authorities activities in identifying, preventing violations in the sphere of turnover of industrial products and in conducting penalties for such violations. Interdepartmental coordination in the implementation of measures to counteract the illegal turnover of industrial products, as well as control over the progress of their implementation, is carried out by the State Commission and the commissions of the subjects of the Russian Federation. The progress of the implementation of measures and activities, the results of monitoring of their implementation are reflected in the annual report of the State Commission on the situation in the sphere of illegal turnover of industrial

	products on the territory of the Russian Federation, which is submitted to the Government of the Russian Federation. In accordance with the Decree of the Government of the Russian Federation dated 05.03.2021 N 551-r, the "Concept of a system for monitoring and assessing the situation in the field of countering illicit turnover in industrial products in the Russian Federation" was approved in order to improve the quality and efficiency of decision-making on prevention, detection, suppression, minimization of consequences of illicit turnover of industrial products in the Russian Federation.
Spain	
Switzerland	

Table D-7 - Point of contact specified for the international exchange of information relating to the counterfeiting of medical product, such as product alerts and analytical reports from laboratory investigations, that has different arrangements from other points of contact (Q21)

Belgium	No
Bosnia and Herzegovina	
Croatia	National contact point and her replacement is from Health regulatory agency.
France	
Hungary	Yes, a colleague of OGYÉI and Police are a point of contact.
Russian Federation	Representatives of Roszdravnadzor and the Ministry of Health of Russia take part in the work of international initiatives to identify and prevent the spread of falsified medical products, such as CMED, WGEO, APEC, WHO Member State Mechanism to address the issue of SF medical products, United Nations Office on Drugs and Crime (UNODC). In accordance with clause 5.15. of the Decree of the Government of the Russian Federation of 30.06.2004 N 323 "On approval of the Regulations of the Federal Service for Surveillance in the Field of Healthcare" Roszdravnadzor interacts in accordance with the established procedure with state authorities of foreign states and international organizations in the established field of activity, and is the only contact point in Russia for cooperation with foreign regulators and organizations on issues of falsification of medical products. As a part of PIC/S membership application process (submitted in December 2020) Roszdravnadzor as a contact point is connected to the system of Handling Rapid Alerts and Recalls Arising from Quality Defects. Roszdravnadzor has also concluded bilateral memorandums of understanding with a number of foreign countries. The documents provide for information exchange on the facts of detection of substandard, falsified, counterfeit products in circulation.
Spain	
Switzerland	

Table D-8 - Is the exchange of information or transfer and receipt of data and evidence between bodies/countries supported and covered by legislation (Q22)

Belgium	Yes. The law of the 25th of March 1964 list the competences of the inspectors of the FAMHP and the exchange of information is listed
Bosnia and Herzegovina	YES
Croatia	In Croatia, several authorities combat the illicit trafficking of medicinal products, exchanging information with prosecuting authorities and thus ensuring uniform prosecution of violations. Agency for Medicinal Products

	and Medical Devices (HALMED) has defined a point of contact for the international exchange of information within the WGEO SPOC and EDQM SPOC network, as well as the Rapid Alert network defined in the Compilation of Community Procedures on Inspections and Exchange of Information issued by the European Commission. Additionally, Customs and Internal Affairs (Police) are involved in the same international exchange of information via the mentioned networks, besides their common channels such as EUROPOL, INTERPOL and police attachés, including joint investigations with those countries. The exchange of information and personal data between law enforcement authorities must be subject to the applicable national and international laws and bilateral or multilateral agreements signed between the respective entities.
France	The exchange of information or the transmission and receipt of data and evidence between agencies/countries is based in particular on the necessary assignment of staff to dedicated units and on the training of such personnel on the use of these cooperation tools. The Ministry of the Interior, through its services and in particular OCLAESP, and through partnership agreements, conducts awareness-raising actions with public authorities and health authorities and maintains close relations with the pharmaceutical industry, wholesale distributors and pharmacies with a view to raising awareness of the threats of organized crime and pharmaceutical crime. Thus, the services of the Police and the Gendarmerie, alongside the Customs and the orders of pharmacists and doctors, participate in the meetings of the LEEM committee (the drug companies), in the work of the G5 (group of eight French laboratories including SANOFI, SERVIER, IPSEN, PIERRE FABRE) and exchanges regularly with the anti-counterfeiting and trademark protection groups of the major pharmaceutical laboratories.
Hungary	The general rules have to be applied to the pandemic time as well. There is a possibility to exchange of information in criminal proceedings. According to Section 261(1) of CCP, in a criminal proceeding, the court, prosecution service, investigating authority or, in cases specified in an Act, the organ conducting a preparatory proceeding may request any organ, legal person, or other organisation without a legal personality to provide data. Exchange of information between countries is ensured by the Medicrime Convention and our national law (on the basis of provisions on spontaneous exchanges of information provided by the Act XXXVIII of 1996 on the international legal assistance in criminal matters and Act CLXXX of 2012 on the judicial cooperation in criminal matters with the Member States of the European Union). Furthermore, the common existing and fast channels of exchange of information, such as Eurojust, EJN, Interpol, work very well in the practice as well. However, there are no national common databases or any other special channels to share information.
Russian Federation	In accordance with the Strategy on Combating Illicit Trafficking in Industrial Products in the Russian Federation for the period up to 2025, the international cooperation of the Russian Federation in the field of combating illicit trafficking in industrial products provides for cooperation with international organizations whose activities are aimed, inter alia, at countering illicit trafficking in industrial products, including the exchange of experience with foreign countries. In accordance with paragraph 4 of the second part of Article 38 and paragraph 1.1 of the third part of Article 41 of the Criminal Procedure Code, the investigator (interrogator) is authorized to give the authority of inquiry in the cases and in the procedure established by the Criminal Procedure Code binding written instructions on the performance of certain investigative actions, other procedural actions, as well as receive assistance in their implementation.

	For example, according to part one of Article 152 of the Criminal Procedure Code, if it is necessary to carry out investigative or search actions in another place, the investigator has the right to carry out them personally or to entrust the performance of these actions to the investigator or the authority of inquiry. The interrogator has the right to carry out them personally or to entrust the performance of these actions to the inquiry officer or authority of inquiry. Orders must be executed no later than 10 days. Part five of the Criminal Procedure Code establishes the procedure for international cooperation in the field of criminal proceedings. In particular, in accordance with the first part of Article 453 of the CPC, if it is necessary to conduct an interrogation, examination, seizure, search, forensic examination or other procedural actions provided for by the CPC in a foreign state, the court, the prosecutor, the investigator, the head of the investigative authority, the interrogator makes a request for their performance by a competent authority or an official of a foreign state in accordance with an international treaty of the Russian Federation, an international agreement or on the basis of the principle of reciprocity. Evidence obtained on the territory of a foreign state by its officials in the course of their execution of orders for the provision of legal assistance in criminal cases or sent to the Russian Federation in an appendix to the order on the implementation of criminal prosecution in accordance with international treaties of the Russian Federation, international agreements or on the basis of the principle of reciprocity certified and transferred in accordance with the established procedure, have the same legal force as if they were received on the territory of the Russian Federation in full compliance with the requirements of Article 455 of the Criminal Procedure Code. In order to combat smuggling, including in the field of illegal movement of falsified medical products across the customs border of the EAEU, on the basis of the FCS of Russia in accordance with the decision of the Council of Heads of Customs Services of the Member States of the Commonwealth of Independent States (hereinafter - the CIS) dated 15.09.2016 № 7/64 within the framework of the activities of the Regional Communication Center for Law Enforcement of the World Customs Organization for the CIS countries, a contact point operates 24 hours on the basis of the international law enforcement communication platform of the World Customs Organization CENcomm. As part of international special customs operations on the CENcomm platform, closed user groups are created to exchange proactive and other law enforcement information about possible upcoming, ongoing and detected offenses in relation to the objects of operations. Representatives of Roszdravnadzor and the Ministry of Health of Russia take part in the work of international initiatives to identify and prevent the spread of falsified medical products, such as CMED, WGEO, APEC, WHO Member State Mechanism to address the issue of SF medical products, United Nations Office on Drugs and Crime (UNODC). As part of the application for membership of the Russian Federation in PIC/S (submitted in December 2020) Roszdravnadzor as a contact point is connected to the Handling Rapid Alerts and Recalls Arising from Quality Defects System.
Spain	In the case of Customs, there is the Convention concluded on the basis of Article K.3 of the Treaty on European Union on mutual assistance and cooperation between customs administrations (Naples II Convention). The Convention covers mutual assistance and cooperation between national authorities in the field of prevention, investigation and prosecution of certain infringements of national and European Union (EU) customs rules. The exchange of information and personal data between law enforcement authorities must be subject to the applicable national and international laws and to bilateral or multilateral agreements signed between the respective governments.

	Where necessary, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL and police attachés, including joint investigations with those countries. Thus, the European Union Agency for Law Enforcement Cooperation (Europol) is a central element of the overall internal security architecture of the Union. The Europol Convention establishes the European Police Office as the institution responsible for structuring police cooperation within the European Union. For its part, the International Criminal Police Organisation—INTERPOL is an international organisation constituted under public international law, facilitating structured police cooperation. The legal basis is to be found in Articles 33 (customs cooperation), 87, 88 and 89 of the Treaty on the Functioning of the European Union (TFEU). As regards the pandemic, at international level, INTERPOL has included in its operation PANGEA on internet drug trafficking, medicines and COVID-19 related crimes. Similarly, EUROPOL through Operation SHIELD on drug trafficking has included this type of crime. The Spanish Guardia Civil actively participates in PANGEA and SHIELD. As regards the transfer and receipt of data and evidence, Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters, which is based on a single instrument for the taking of cross-border criminal evidence in the European Union, is available at European Union level. The Directive, proposed under the Spanish Presidency as a result of a slow and complex negotiation process, regulates the European Investigation Order, which will be issued for the purpose of obtaining one or more specific investigative measures to be carried out in the executing State, with a view to obtaining evidence or gathering evidence already in the possession of the executing authority. The Directive was transposed by Law 3/2018 of 11 June, amending Law 23/2014 of 20 November on mutual recognition of criminal decisions in the European Union, to regulate the European Investigation Order. The European Investigation Order creates a single regime for the taking of evidence and also includes measures involving the taking of evidence in real time, continuously or over a certain period of time, providing that, where necessary, the issuing and executing States may agree among themselves practical arrangements in order to reconcile the differences between their national laws.
Switzerland	In accordance with the Convention and following the entry into force of the revised TPA on 1 January 2019, Swissmedic became the national SPOC according to Art. 69, para. 4 of the new legislation. There is close cooperation between this national SPOC division and the Swissmedic Penal Division, which is responsible for prosecuting and penalising violations relating to the manufacture, supply and trafficking of illegal therapeutic products. Violations in connection with the use and dispensing of therapeutic products fall under the competence of the cantonal prosecution authorities. Swissmedic's Penal Division, the Office of the Attorney General (OAG) and the cantonal prosecuting authorities have a very close, active and efficient exchange of information, thus ensuring uniform prosecution of violations relating to the TPA throughout Switzerland (cf. answer 1). The exchange of confidential data between the (federal and cantonal) enforcement authorities in Switzerland and between the federal enforcement authorities and foreign authorities/institutions is enabled by law, cf. Art. 63 and 64 TPA. With regard to criminal proceedings, the cantonal prosecution authorities have an obligation to inform Swissmedic of the initiation of preliminary proceedings relating to the TPA (Article 90, para. 3 TPA). Furthermore the Penal Division of Swissmedic may exercise the rights of a private claimant in the proceedings. Additionally, the Ordinance on the Notification of Cantonal

	Criminal Decisions requires the cantonal prosecution authorities to inform (i.e. supply with a copy) Swissmedic about their criminal decisions based (also or solely) upon the TPA (cf. Article 3 No. 15). In the international context, Switzerland ratified the European Convention on Mutual Assistance in Criminal Matters (entry into force 20 March 1967). The prosecutor's offices in Switzerland fulfil mutual legal assistance in close cooperation with the Federal Office of Justice, based on the Federal Act on International Mutual Assistance in Criminal Matters (Mutual Assistance Act, IMAC). On the police level, the Federal Office of Police (fedpol) is the central agency for police co-operation. The office helps to build and maintain contacts between the cantonal police and law enforcement agencies, and between them and international partners. Within fedpol, the Directorate for International Police Co-operation, with its Operations Centre, and the Directorate of Federal Criminal Police are primarily entrusted with various aspects of international co-operation. The latter is part of the "coordination group Medicrime", which regularly holds meetings with Swissmedic and the Federal Customs Administration.

Detection – An understanding and appreciation of the various measures that may be proactively taken during a pandemic to detect counterfeit medical products and to prevent them from reaching patients

Table E-1 - legislative or other measures to ensure that industry can promptly report suspicions or detections of counterfeit medical products and similar crimes involving threats to public health, to any particular authority; Established or ad hoc procedures and processes for this reporting? (Q23)

Belgium	Yes. The FAMHP has created a Rapid Alert system to alert the industry when (suspected or confirmed) falsifications of medicines have been found. This system is also used to alert the industry of thefts of medicines. If these medicines are found within our supply chain the concerned distributor or manufacturer will contact us so we can investigate further. And the Falsified Medicines Directive has made it mandatory for the industry to put up a system to make it easier to detect falsified medicines within the legal supply chain.
Bosnia and Herzegovina	In accordance with positive legal standards, any natural and legal person is entitled to report to the competent authorities, including the police, orally or in writing, any type of suspicion of illegal acts related to the counterfeiting of medicines and similar crimes. In addition, in accordance with the legal provisions, any person is obliged to report a criminal offence, and is liable to criminal liability if he does not act in accordance with the above (criminal offence "Failure to report a criminal offence or perpetrator")
Croatia	According Medicinal Product Act article 120. a holder of the authorisation for wholesale distribution are obliged to immediately notify the Agency of any falsified medicinal product received or offered or any medicinal products suspected of being falsified. Wholesalers and brokers are obliged to instantaneously inform Agency about suspicious medical products according to Ordinance on good practice in the distribution of medicinal products, on issuing authorisations for wholesale distribution of medicinal products, registration for brokering of medicinal products and on issuing certificates on good practice in wholesale distribution of medicinal products, article 44, 61,62. Article 6 of Ordinance on the suspension of the placement on and withdrawal of medicinal products from the market : The holder of the marketing authorisation for the medicinal product, holder of the authorisation for the parallel import of the medicinal product, manufacturer of the medicinal product, importers and wholesalers included in manufacturing or in performing wholesale trade of medicinal products are obliged to inform the Agency in writing of each observed case from Article 2 of this Ordinance. Article 2 in the cases that could be the reason for the suspension of the placement on and withdrawal of medicinal products from the market from Article 62 of the Medicinal Products Act (hereinafter: the Act), are obliged to notify the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) in writing. In article 62 one of the reason is that the medicinal product is falsified.
France	Pharmaceutical establishments are required to report to the National Agency for the Safety of Medicines and Health Products any falsification or suspicion of falsification of medicinal products under Articles R. 5124-48-2 and R. 5124-36 of the Public Health Code.

	Pharmaceutical establishments, pharmacies and pharmacies for domestic use are required to report any theft of narcotic drugs and psychotropic drugs to the police, the Agency and the Regional Health Agencies under Articles R. 5132-80 and R. 5132-95 of the same Code. With a view to optimizing traffic detection and improving intelligence cross-checking capabilities, initiatives are being undertaken with the private sector. Thus, an agreement has been set up by OCLAESP with the G5 which brings together eight French laboratories including Ipsen, Sanofi, Servier and Pierre Fabre. The private sector faced with problems of falsification of its production has developed devices for identifying illicit sites of sale on the Internet which constitute important resources for detecting trafficking. In this way, OCLAESP has enabled the existence of an effective communication channel with industry when it suspects or detects counterfeit medical products and similar offences threatening public health, allowing for very rapid reporting. Apart from this convention, there are many links of trust with other players in the industry for which OCLAESP is essential in this area and very easily accessible. In terms of public health, all the French authorities in charge of these issues have initiated exchanges of information by collaborating directly with: the National Agency for the Safety of Medicines and Health Products (ANSM), the National Agency for Food, Environmental and Occupational Health and Safety (ANSES), the National Agency for Veterinary Medicinal Products (ANMV), the National Order of Pharmacists, the Orders of Physicians, the National Brigade for Veterinary and Phytosanitary Investigations (BNEVP), the Regional Directorates for Enterprises, Competition, Consumption, Labour and Employment (DIRRECTE), the Directorate General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF), the French Agency for the Fight against Doping (AFLD), the Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (CNAMTS), etc. Where an authority with the power to monitor health matters finds or detects a suspicion of damage to public health, it shall inform the judicial authority thereof by means of Article 40. This information then leads to the initiation of public action by carrying out investigations by the police forces.
Hungary	Pursuant to Section 17(1) of the Act XCV of 2005, stakeholders of marketing authorization and pharmacists engaged in the wholesale distribution of medicinal products or in the supply of medicinal products to the public, retail suppliers of medicinal products other than pharmacies, as well as the doctors administering the medicinal products shall report any suspected deficiency in the quality of a medicinal product or production batch, and information on any suspected counterfeit medicinal product to the government body for pharmaceuticals (OGYÉI) without delay upon gaining knowledge about such deficiency. The information may be sent in any way but there is also a dedicated email address for this purpose which is used by health professionals and by the public too. According to Section 376(1)-(2) of CCP, any person may file a crime report regarding a criminal offence subject to public prosecution. Moreover, a member of an authority, a public officer, and, if required by law, a statutory professional body shall file a crime report regarding a criminal offence subject to public prosecution it becomes aware of in its official competence or in his official capacity, respectively.
Russian Federation	In accordance with the Federal Law "On the procedure for reviewing appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, the appeal of citizens and legal entities to the state body is necessarily subject to consideration. Such an appeal may serve as a basis for conducting control and supervisory measures. Article 57 of the Federal Law of 12.04.2010 No. 61-FZ "On the Circulation of Medicines" prohibits the sale of falsified, substandard and counterfeit medicines.

	Art. 4, paragraph 26.1 of the Federal Law of 12.04.2010 No. 61-FZ established that the MAH (marketing Authorisation Holder) of the medicine is responsible for the quality, efficacy and safety of the medicine. Upon receipt of information about a possible substandard quality of a medicine batch, the holder informs Roszdravnadzor about the decision to withdraw the batch of a medicine, which is published on the Roszdravnadzor website in the form of an information letter for subjects of medicines circulation. The actions of Roszdravnadzor are reflected in the relevant SOPs. On the official website of Roszdravnadzor in the section "Search for withdrawn medicines" information is provided on medicines that have been withdrawn from circulation due to their substandard quality: https://roszdravnadzor.gov.ru/services/lssearch. By Art. 38 of the Federal Law of 21.11.2011 N 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation" (as amended and supplemented, entered into force on 01.10.2021) it is prohibited to import into the territory of the Russian Federation as well as to sell falsified, substandard and counterfeit medical devices. Roszdravnadzor information letters on monitoring the safety of medical devices are posted in the electronic service "Information letters about medical devices": https://roszdravnadzor.gov.ru/services/unreg In the territorial bodies of the Ministry of Interior of Russia reception, registration and permission of statements and reports about crimes is carried out in accordance with the Instruction on the procedure for receiving, registration and permission in the territorial bodies of the Ministry of Interior of the Russian Federation of statements and reports of crimes, administrative offenses, incidents, approved by the order of the Ministry of Interior of Russia dated August 29, 2014 No. 736 (hereinafter referred to as the Instruction). In accordance with clause 8 of the Instruction statements and reports of crimes, regardless of the place and time of the crime, as well as the completeness of the information contained in them and the form of submission, are subject to compulsory reception in all territorial bodies of the Ministry of Interior of Russia. Registration in the Book of records of statements and messages about crimes, administrative offenses, incidents (hereinafter - BRMC) of statements and messages about crimes is carried out regardless of the operational service area immediately and 24 hours in the duty units of the territorial bodies of i of the Ministry of Interior of Russia (paragraph 23 of the Instruction). Electronic statements are printed on paper, further work is carried out with them as with written statements about crimes, administrative offenses, incidents in the manner prescribed by paragraph 11 of the Instruction. Statements of crimes contained in written applications sent through postal operators with the delivery of written correspondence to the building of the territorial body of the Ministry of Interior of Russia, official sites, facsimile communications, federal courier communications and special communications, mailbox, received during a personal reception are accepted by the division of office work and regime of the territorial body of the Ministry of Interior of Russia, are registered in the prescribed order and are sent by the head (chief) of the territorial body of the Ministry of Interior of Russia to the duty unit of the territorial body of the Ministry of Interior of Russia for immediate registration with the BRMC (clause 12 of the Instruction). Section V of the Instruction establishes the procedure for monitoring compliance with the procedure for receiving, registering and resolving statements and reports of crimes. In particular, paragraph 72 of the Instruction stipulates that the head (chief) of the territorial body of the Ministry of Interior of Russia bears personal responsibility for compliance with the law when accepting, registering and resolving statements and reports of crimes; ensures daily control over the deadlines for resolving statements and reports

	of crimes, as well as the correctness of maintaining the BRMC with a record of this in the book of reception and delivery of duty.
Spain	As mentioned above, the Spanish Medicines and Health Products Agency (Agencia Española de Medicamentos y Productos Sanitarios) has a mailbox medicamentos.falsificados@aemps.es to report cases of medicinal products, both for human and veterinary use, which are falsified or suspected of being falsified, which are detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing or importing laboratories, wholesale drug distribution warehouses, and healthcare professionals. As regards information channels, a first channel is the Social Security Investigation Group (GISS) of the Criminal Police Technical Unit. The Ministry of Health forwards to the GISS any reports or suspicions of criminal offences which it is aware of, either directly, from the Autonomous Communities (Regions) or from the international spheres with which it is linked. The GISS studies, analyses and passes them on the basis of the location of the main event to the various investigation units of the Spanish Guardia Civil, which carry out the operational activities necessary for their investigation. Another way of intelligence (input/output) to the GISS is through Spanish agencies; such as the Spanish Medicines and Health Products Agency (AEMPS), the Spanish Agency for the Protection of Health in Sport (AEPSAD) or the Spanish Food Safety and Nutrition Agency (AESAN), Official Associations and other bodies; At international level, information is shared with EUROPOL, INTERPOL, Police Attachés, other International Agencies and with different countries. Another channel would be the Spanish Guardia Civil units that are aware, either ex officio or through the various national or international channels, of these crimes. These units would carry out the investigation itself by assuming responsibility of the investigation, or if this is not possible, they would transfer it to another superior or competent unit, but always in the Spanish Guardia Civil. The AEMPS, together with the Ministry of Health, drew up a number of instructions for the purposes set out: Instructions for reporting suspicions of falsified medicinal products identified by manufacturers in relation to safety features In accordance with Delegated Regulation (EU) No 2016/161, Instructions for reporting suspicions of falsified medicinal products identified at distribution entities in relation to safety features in accordance with Delegated Regulation (EU) No 2016/161 and Instructions for the notification of suspicions of falsified medicinal products identified in pharmacy offices or services in relation to safety features in accordance with Delegated Regulation (EU) No 2016/161. Contact points have also been established in the Autonomous Communities (Regions) for the notification of suspected falsifications of medicinal products .
Switzerland	Reporting of suspected trafficking and counterfeiting in medicinal products has been introduced in the Therapeutic Products Act as a mandatory requirement for industry with the ratification of the Medicrime Convention. A specific form and information sheet are provided on the Swissmedic and Medicrime websites, and procedures are in place for such reporting. The medical devices industry reports suspicions without legal obligation directly to the central Medical Devices Surveillance contact point.

Table E-2 - market sampling programme established to detect counterfeit medical products on the market; If so, which authority is responsible for this; Is this system sustainable in times of pandemic having regard to the additional demands placed on analytical laboratories and testing services by the impact of the pandemic; Are there oversight arrangements to ascertain the effectiveness of these measures? (Q24)

Belgium	There is a market sampling programme to detect non conformities in medicines, not only for falsified medicines. Detection Medical Devices: During the lockdown period there was a sampling plan but now it is cancelled because there are no longer laboratories that are able to execute tests on particular medical devices. A sample plan was temporarily developed in response to the introduction of the ATP (Alternative Testing Protocol) for mouth masks.
Bosnia and Herzegovina	YES, an inspection system is set up for regular monitoring of the market, wholesalers (regular monitoring of medicines, annual and at least once every five years)
Croatia	Market surveillance through monitoring the quality and safety of medical products in the market including falsified medicines is included in Strategic plan of Agency for Medicinal Products and Medical Devices (HALMED). According to the Medicinal Products Act (Official Gazette 76/13) Agency for medicinal products and medical devices is responsible for regular quality control according to the annual sampling plan (Article 176) and for extraordinary, unscheduled quality control in the cases of quality defects and suspected falsified medical products (article 177). Article 176 (1) The Agency shall conduct quality control of medicinal products taken from distribution by the pharmaceutical inspection at least once in five years for each pharmaceutical form and each strength of the medicinal product. (2) The Agency may conduct quality control of galenic preparations taken from distribution by the pharmaceutical inspection. Article 177 (1) Unscheduled quality control shall be conducted at the request of the Ministry or the Agency in the event of any unusual signs or suspected quality defects or suspected falsified medicinal products or galenic preparations, and it shall be carried out by the Agency. Effectiveness of this measures is assessed in yearly Activities Report (presented also to the Government) and Management Review. Pharmaceutical inspection of the Ministry of health is responsible for sampling medical devices from the market according article 66. , 67. and 68. of Medical Devices Act. There is no structured market surveillance programme for medical devices.
France	France participates in the international operation "PANGEA XI", the main internationally coordinated operation to combat trafficking in illicit health products. Initiated in particular by Interpol and the World Customs Organization (WCO), in the interest of patients and consumers, it takes place simultaneously in a hundred countries, including France. For its participation, France has implemented an inter-ministerial mechanism coordinated between the customs, gendarmerie and police services, also involving the regulatory and control authorities responsible for human medicines and animal health. The committed services OCLAESP, DNRED (National Directorate of Intelligence and Customs Investigations), SNDJ (National Judicial Customs Service), ANSM (National Agency for the Safety of Medicines and Health Products), BNEVP (National Brigade of Veterinary and Phytosanitary Investigations)) work in the field, but also on the Internet, to dismantle illegal sites offering unauthorized health products.

	In France, the success of operation PANGEA is confirmed again this year: more than 466,000 illicit health products and one tonne of bulk products were seized; 13 judicial investigations have been opened and to date no indictment or person imprisoned. More than 70 per cent of the goods seized came from Asia (mainly India and Singapore). The majority of seizures took place on major airport platforms but also in road freight. The results of analyses carried out by the Joint Laboratory Service (SCL) of the Ministry of Finance on certain products seized during the operation made it possible to detect illegal substances presenting a proven risk to the health of the consumer. Other products analysed did not contain any active substance or active ingredient other than that advertised.
Hungary	During the pandemic primarily customs were coordinated by programs (actions) to detect counterfeit medical products with the participation of many authorities. World Customs Organisation launched Operation STOP and Operation STOP II to protect the public against counterfeit/illicit medicines and other sub-standard medical supplies and equipment in the context of the COVID-19 pandemic. The Hungarian participation was coordinated by the National Tax and Customs Administration. Beyond the above, the Ministry for Innovation and Technology coordinated market sampling programmes. Regarding veterinary medicinal products, any suspected adverse events should be reported and collected according to Articles 73-81 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. The Hungarian competent authority is the National Food Chain Safety Office (NÉBIH). Information can be sent to NÉBIH in any possible form, but there is also a dedicated e-mail address and an online reporting page on the website of NÉBIH (https://portal.nebih.gov.hu/-/mellekhatasok-pharmacovigilance-esetek-bejelentese). A coordinated, annual market sampling programme is in place in the field of veterinary medicinal products as well. The list of products for sampling is determined on a risk based approach. Collected samples are tested by the OMCL laboratories of the central competent authority, NÉBIH
Russian Federation	Article 9 of the Federal Law of April 12, 2010 № 61-FZ "On the Circulation of Medicines" provides for the following control and supervisory measures in the implementation of federal state control in the field of circulation of medicines: 1) documentary verification; 2) on-site inspection; 3) selective quality control; 4) test purchase; 5) inspection visit; 6) monitoring compliance with mandatory requirements (safety monitoring) (pharmacovigilance). Article 95 of the Federal Law of 21.11.2011 No. 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation" provides for the following control and supervisory measures in the implementation of federal state control (surveillance) over the circulation of medical devices: 1) documentary verification; 2) on-site inspection; 3) selective control; 4) test purchase; 5) inspection visit; 6) monitoring compliance with mandatory requirements (safety monitoring). Control and surveillance activities are carried out in accordance with the requirements of the Federal Law of July 31, 2020 No. 248-FZ "On State Control (Surveillance) and Municipal Control in the Russian Federation". In accordance with Article 65 of Federal Law №. 248-FZ, as part of control (supervisory) actions, sampling (samples) may be carried out, among other measures.

	Federal state control (surveillance) in the field of circulation of medicines is carried out in accordance with the Decree of the Government of the Russian Federation dated June 29, 2021 №. 1049. Federal state control (surveillance) over the circulation of medical devices is carried out in accordance with the Decree of the Government of the Russian Federation dated June 30, 2021 № 1066. In accordance with the Regulation on the Federal Service for Surveillance in Healthcare, approved by Decree of the Government of the Russian Federation № 323 dated June 30, 2004, state control over the circulation of medical devices and medicines is attributed to the powers of Roszdravnadzor. Selective quality control of medicines for human use is conducted in accordance with the Order of Roszdravnadzor No. 5539 dated August 7, 2015. When forming a plan for quality selective control, Roszdravnadzor, among other, takes into account: data on the identification of substandard and falsified medicines, information on the quality of medicines contained in appeals and statements of citizens, legal entities, individual entrepreneurs, information from state authorities, local governments, from the media. A group of medicines for the treatment of coronavirus infection was included into the Plan of selective quality control of medicines for 2021, approved on 25.12.2020 by Roszdravnadzor Letter No. 01i-2451/20 (posted in public access on the official website of Roszdravnadzor https://roszdravnadzor.gov.ru/drugs/qualitycontrol/documents/b579). As a part of selective control released batches of medicines for COVID-19 treatment are selected and tested in federal laboratories.
Spain	The AEMPS is responsible for monitoring, with the cooperation of the Autonomous Communities and the pharmaceutical services of the Government Delegations and Sub-Delegations, that there are no unauthorised, counterfeit or adulterated products on the market. There is also a border pharmaceutical control over the external trade of medicines, which would prevent the entry of counterfeits. The AEMPS has an e-mail address (medicamentos.falsificados@aemps.es) for reporting cases of falsified or suspected medicinal products for human and veterinary use detected in the legal distribution and supply channels. Such notifications may be sent by marketing authorisation holders, manufacturing laboratories or importers, medicines distribution entities and healthcare professionals. This mailbox is continuously followed up in order to allow for rapid intervention by the health authorities when needed. In addition, the AEMPS has a system for reporting quality incidents of medicinal products for human use via email alertas.calidad@aemps.es which is continuously monitored. These notifications may be made by the pharmaceutical industry, the competent health ministers of the Autonomous Communities (Regions), and by individuals or other entities (hospitals, pharmacies, wholesale warehouses, official pharmacists' colleges, etc.). These communications are assessed by the AEMPS, and in case of suspicion of falsification of medicinal products, appropriate investigations would be carried out to confirm this fact and to take the necessary action to secure its immediate withdrawal. On the other hand, each year the AEMPS, in collaboration with the Autonomous Communities, develops a programme to monitor medicines on the market to verify that their quality is maintained in the distribution and dispensing chain. The control plan includes the verification of the placing on the market of medicinal products, the monitoring of materials such as labelling and package leaflet or their compliance with the authorised dossier to the analysis of the medicinal product in question, and the inclusion of the medicinal products in that programme is carried out on the basis of risk criteria. The programmes are designed every year, and the risk of falsification of each medicine is a factor taken into account to include medicines in the

	study. For example, anabolic steroids or PDE-5 inhibitors, which have a higher risk of being affected by counterfeits, have been included. Such a system would also allow for the possible presence of an illegal medicinal product in the distribution chain. These samples would be analysed by the AEMPS Official Control Laboratory with sufficient technical and human resources to have analytical capacity in relation to tests to detect falsified medicinal products. The laboratories holding the marketing authorisation for medicinal products also collaborate with the AEMPS to determine whether the sample in question is original or falsified. In medical devices there is no specific sampling programme for the identification of counterfeit products. Given the wide variety of medical devices on the market and their specific characteristics with product sampling, it is not easy to detect counterfeits. In medical devices, in the vast majority of cases counterfeits are based on the documentation accompanying the device (declaration of conformity, CE marking certificate, instructions, etc.) rather than on the device itself. Companies falsify the documentation relating to the CE marking in order to be able to place the product on our market. It is through the annual market control campaigns and, in particular, the usual market control activities and border inspection, that medical devices with falsified documentation are more detected. The Spanish Medicines and Health Products Agency is the competent authority for medical devices. The Autonomous Communities also have competence in the field of market control. Finally, with regard to the activities of the analytical laboratories, the Agency has no competence to regulate activities and that action has been taken only in respect of non-compliances observed in the products they use.
Switzerland	For medical devices, a legal basis for establishing annual market surveillance plans for regional authorities with central reporting has been introduced. Because of the focus on ad hoc measures against cases of non-conforming medical devices during the pandemic, a prospective sampling programme had to be postponed. (…) there is a large program of "geplante Marktüberwachung" (annual plan for market surveillance) which in the beginning of each year defines the sampling of medical products. Both annual plans for sampling, one with focus on the legal, one plan with focus on the illegal supply chain. The OMCL (Official Medicines Control Laboratory) confirmed that their laboratory analyses would also detect if the medicines analyzed were counterfeit. no counterfeit medicinal products in Swiss packaging have ever been observed.

Table E-3 - Do sampling programmes, mentioned in question Table E-3, above, cover public procurement of medical products to detect counterfeit medical products being used in the public health system, such as in hospitals, and not procured for supply by sale to the trade or public? If not, are there arrangements to introduce such a programme (Q25)

Belgium	As mentioned in the answer to question 24 : the market sampling programme detects non conformities in medicines in the legal supply chain (distributors, pharmacies and hospitals.) The Belgian Law does not allow the purchase of samples of (possible) falsified medicines outside this legal chain. However the legislation will change and in the future, it will be possible to do test purchases of (possibly) falsified medicines p.e. through the internet.
Bosnia and Herzegovina	As a preventive measure, purchases are made only from approved licensees / wholesalers

Croatia	Agency for Medicinal Products and Medical Devices (HALMED) has an OMCL Division which is part of EDQM OMCL network. As many others OMCLs of the GEO, beside planned market surveillance testing of all medicines (with products selected according to risk-based criteria) Croatian OMCL do the analysis of falsified and illegal medicines on behalf customs, police, enforcement/food inspectors and courts and also a targeted analysis of the most counterfeited medicines which were recognized and selected at the network meetings. According to the Medicinal Products Act (Official Gazette 76/13,) regular quality control according to the annual sampling plan (Article 176) and extraordinary quality control in the cases of quality defects and suspected falsified medical products (Article 177) applies to all medical products regardless of the place of purchase
France	
Hungary	Besides pharma serialisation (verification of the authenticity and identification of every individual pack of a medicinal product) which started at the EU level in 2019, there is currently no other program to detect counterfeit medical products in the public health system. (The Ministry of Innovation and Technology had been coordinating market sampling programmes before, but the Ministry ceased to exist on 23 May 2022.)
Russian Federation	Federal state control (surveillance) may be applied to any medical products in circulation on the territory of the Russian Federation including in a wholesale organization, in a retail network, in a medical institution. The implementation of a system to monitor the movement of medicines (Track and Trace) contributed to the identification of offenses in the sphere of circulation of expensive medicines. In particular, even at the stage of the experiment on the implementation of the Track and Trace system in the Russian Federation facts were revealed when medicines were purchased under government contracts, stolen and re-sold under government contracts in other regions of the Russian Federation. An example of such an investigation is given in the press release of the territorial body of Roszdravnadzor: https://78reg.roszdravnadzor.gov.ru/news/23617. In accordance with Article 67 of Federal Law No. 61-FZ of 12.04.2010 "On Circulation of Medicines", mandatory labelling of medicines has been introduced since July 1, 2020. At the moment, an experiment on the labelling of wheelchairs related to medical devices has been completed on the territory of the Russian Federation The most important prospect in the circulation of medical devices, especially high-tech equipment and mass-consumption products, should be the implementation of mandatory labelling of medical devices by means of identification and the creation of an information system that allows identifying a unit of a medical device based on the information embedded in this labelling. Relations aimed at ensuring state and municipal needs in order to increase the efficiency and effectiveness of procurement, to ensure publicity and transparency, to prevent corruption and other abuses are defined by Federal Law No. 44-FZ of 05.04.2013 "On the contract system in the procurement of goods, works, services for state and municipal needs". Article 94 provides for the possibility for the customer to conduct an examination of the delivered goods. The execution of the requirements of federal legislation is controlled by the Prosecutor General's Office.
Spain	The vast majority of medicines included in the control programmes are prescription-only medicines which are publicly funded and fall within the pharmaceutical provision of the National Health System. Many are hospital used, but this characteristic has so far not been considered to prioritise the inclusion of medicinal products in the control programmes.

	To include these medicinal products, it is not necessary to establish specific agreements; They can be included in the programme and sampled without agreement. As regards sanitary products, as indicated above, there are no specific sampling campaigns. However, market surveillance campaigns and routine control activities cover all types of products including medical devices for professional use used in the health system.
Switzerland	Answer included in Question 24. (There are no current sampling programmes, but these will be introduced for medical devices programmes; no details are available as yet).

Table E-4 - Are there laws and policies in place to enable customs services to detect, detain and act on a counterfeit medical product, as defined in Article 4.j, different to the intellectual property counterfeiting (Q26)

Belgium	The Regulation (EU) 608/2013 concerning customs enforcement of intellectual property rights gives Customs the legal basis to act in cases of counterfeit. They can act on their own initiative if they suspect a counterfeit, but it will only be considered a counterfeit if the rights owner confirms it. Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 gives Customs the possibility to block suspicious shipments for 3 days in which period they can contact the competent authority, the FAMHP in case of medical products, and ask their advice concerning this shipment. Should the shipment contain falsified medicines the case is transferred to the FAMHP who -depending on the severity of the case- will conduct the investigation itself or will contact a Prosecutor.
Bosnia and Herzegovina	Yes, in accordance with the provisions of the Basel Convention on the issue of waste management, which includes medical waste. An appropriate permit is required. Trade in medicines is regulated by the Pharmaceutical Trade Act.
Croatia	Yes, if customs officers would detect suspected counterfeit medical products (as defined in Article 4.j) they would inform Pharmaceutical inspection. Regarding the source of authority for the actions of customs authorities in case of irregularities, the origin is found in the provisions of Article 47 of the Customs Code of the Union (Regulation (EU) No. 952/2013 of the European Parliament and of the Council of October 9, 2013 on to the Customs Code of the Union; OJ L269/1), Article 47 Cooperation between authorities.
France	
Hungary	Yes, the general rules have to be applied to the pandemic time as well. Minor cases concerning counterfeiting of medicinal products fall under the competence of the National Tax and Administration Office, which investigates these infractions during an infraction procedure (Section 119/A of the Act II of 2012 on infractions, on infraction proceedings and on infraction registration system). Section 199/A – Pharmacy infraction (1) Any person, who a) offers, hands over, acquires or keeps in quantities not exceeding an unjustified quantity a counterfeit or counterfeited medicinal product or veterinary medicinal product, or a medicinal product or veterinary medicinal product not licensed in Hungary, b) keeps an unjustified quantity of a substance or preparation that qualifies as a prescription medicine in Hungary, commits an infraction.

	(2) Proceedings for an infraction under paragraph (1) shall fall within the competence of the National Tax and Customs Administration. (3) For the purposes of paragraph (1), unjustified quantity means a quantity that is clearly not intended for the purpose of satisfying the personal needs of a specific patient.
Russian Federation	In accordance with the Customs Code of the EAEU, the customs authorities, within their competence, ensure the fulfillment of objectives to protect human life and health, rights to intellectual property, the rights of consumers of goods imported into the Russian Federation. The crimes against which the Medicrime Convention is directed are investigated regardless of intellectual property rights. The customs authorities are authorized to amount protocols on the administrative offense (AO) under Article 6.33 of the Code of Administrative Offenses of the Russian Federation within their competence - for offenses related to the import into the territory of the Russian Federation of falsified medicines, medical devices, nutritional supplements, counterfeit medicines and medical devices, if these actions do not contain a criminal offense (part 1 of article 6.33 of the Code of Administrative Offenses of the Russian Federation). In the event that customs officials identify other AOs (production, sale, realization) under Article 6.33 of the Code of Administrative Offenses of the Russian Federation, such materials are sent to the territorial bodies of Roszdravnadzor in accordance with Cooperation Agreement. At the same time, the Customs Code of the Eurasian Economic Union grants customs authorities powers in the field of regulating the protection of intellectual property rights, known as ex officio. It provides for the possibility to suspend the release of goods for 10 days if the customs authority has detected signs of violation of the rights of the copyright holder to intellectual property objects. At the request of the copyright holder this period can be extended up to 10 more days.
Spain	Customs makes requirements for the importation of medicinal products, including the provision of different documentation. If those conditions are not met, the customs office refuses to release the goods, that is to say, their importation. Customs is responsible for all matters relating to smuggling and is covered by Organic Law 12/1995 of 12 December 2015 on combating smuggling in order to treat counterfeits (regardless which product the are of) as a prohibited genus, as defined in the Law itself. 'Article 1.12. "Prohibited genres": All those whose import, export, circulation, holding, trade or production is expressly prohibited by a treaty or convention concluded by Spain, by a legislative provision or by a regulation of the European Union. The prohibition shall be limited, in respect of each sex, to the performance of the activity or activities expressly laid down in the prohibition rule and for such period as may be stated therein." 'Article 2.2. The crime of smuggling is committed, provided that the value of the goods, merchandises, genres or effects is equal to or greater than EUR 50,000, by any of the following: (b) Import, export, trade, holding, movement of: Stagnant or prohibited genera, including their production or rehabilitation, without complying with the requirements laid down by law". Customs surveillance resolves cases of forgery by requesting the customs administrator to control the exit of goods, in order to make a kind of 'controlled delivery' of these counterfeits in order to prosecute the offenders. With regard to the tools available, risk analysis is used at customs level, based on certain parameters, in collaboration with right holders and experts.
Switzerland	The laws enable customs services to take action without reference to a rights holder notwithstanding that the same medical product may also infringe an intellectual property right. Customs services take measures independently of each other, both according to TPA (public law) and the IPR (private law) .Based on national intellectual property legislation, the FCA is – if requested

	by the rights holder - authorised to intercept counterfeits and to inform the rights holder of the intellectual property if there is any suspicion of the imminent transport of goods that unlawfully bear an intellectual property right. In addition, if no request to protect an intellectual property right is made, based on the Therapeutic Products Act, the FCA is entrusted with the enforcement of this Act. The FCA may, within its jurisdiction and in close collaboration with Swissmedic, take all administrative measures necessary to enforce this Act. In particular, the FCA may hold back or seize therapeutic products which endanger health or which do not comply with the regulations of this Act for the initiation of further measures by Swissmedic. Moreover, if the import, transit and export of therapeutic products also involves a violation of the Customs Act or the Value Added Tax Act, the FCA shall prosecute and judge the offences.

Investigation and Prosecution: ability to investigate and prosecute offenders for intentional crimes related to counterfeit medical products and similar crimes, in particular during a pandemic

Table F-1 - the criminalisation of offences achieved in order to enable effective investigation and prosecution. (Q 27)

Belgium	a. Medical Products Article 4.a: It corresponds. In our national law there is a definition for medicines for human use and veterinary use (Law of the 25th of March 1964 on medicines article 1,§1,1) and a definition for medical devices (Royal Decree of the 18th of March 1999 on Medical Devices article 1,§2,1° ; this Royal Decree refers to the law on Medicines.) b. Counterfeiting Article 4.j: We use the term falsified since counterfeit has a tendency to be interpreted as an infraction on IPR. The definition of a falsified medicine in the law of the 25th of March 1964 on medicines is the same as the definition of a falsified medicine in the Falsified Medicines Directive 2011/62 : “Any medicinal product with a false representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used”. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.’; So we include the falsification of documents in the definition of a falsified medicine. The notion of counterfeit corresponds with the notion of falsified since the Medicrime Convention does not target IPR infractions. c. Articles 5 and 6, and 4.a and 4.jManufacturing of counterfeits : law of the 25th of March 1964 on Medicines article 16 (medicines) and 16bis (medical devices) -> criminal sanction. Supplying, offering to supply, and trafficking in counterfeits : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction d. Articles 8 and 4.a: Similar crimes involving threats to public health : law of the 25th of March 1964 on Medicines article 16 and 16bis (medical devices) -> criminal sanction. e.Falsification of documents Article 7: law of the 25th of March 1964 on Medicines article 16 -> criminal sanction f.Legal persons Article 11: The Criminal Code article 5 says that ‘A legal person may be held liable for offences that are either intrinsically linked to its purpose or its interest, or which are committed

	on its behalf as evidenced by the specific circumstances. The liability of legal persons does not exclude that of natural persons who are perpetrators of the same acts or who have participated in them. This applies to every legal person that is established in Belgium.
Bosnia and Herzegovina	The provisions of the MEDICRIME Convention have not been transposed into criminal law in Bosnia and Herzegovina as required by the Convention. The Ministry of Justice of Bosnia and Herzegovina has established a working group to find adequate solutions that will eliminate the identified gaps and improve the current provisions of the Criminal Code of Bosnia and Herzegovina and the Code of Criminal Procedure of Bosnia and Herzegovina. regulation and, in order to harmonize criminal legislation in Bosnia and Herzegovina, to initiate possible amendments to criminal legislation at the entity and district level of Brčko. Within the framework of the work of this working group, the provisions of the Convention that need to be implemented in criminal legislation in Bosnia and Herzegovina will be examined. Until the Convention is fully implemented, the criminalization of this type of criminal offence is carried out by the provisions of the Criminal Code of Bosnia and Herzegovina which prescribes the criminal offences of illicit trade (Article 212) and illicit production (Article 213), which cover all types of goods and production prohibited by the regulations of Bosnia and Herzegovina or international regulations, and medical products and equipment. Similar provisions are contained in the criminal laws of the entities and the brcko district.
Croatia	Article 185 of the Criminal Code Counterfeiting of Medicines or Medical Products Article 185 of the Criminal Code (1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years. (2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia. (3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years. (4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices. The definition of medicinal product and medical devices are in the relevant Medicinal Products Act Article 3 For the purposes of this Act, the following terms shall bear the following meanings: 1. Medicinal product shall mean: - any substance or combination of substances presented as having properties for curing or preventing disease in human beings, or - any substance or combination of substances which may be used or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical

	diagnosis, Medical Devices Act Article 3 For the purposes of this Act the following definitions shall apply: 1. 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; b. To what extent does the notion of 'counterfeiting' in internal law fully corresponds with the definition by Article 4.j as regards medical products? What steps have been taken to ensure that this has been or will be achieved? Medicinal Products Act Article 3 49. Falsified medicinal product any medicinal product which is deliberately and fraudulently mislabelled with respect to: a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder, or c) its history, including the records and documents relating to the distribution channels used. This definition shall not apply to unintentional quality defects and to infringements of intellectual property rights, c. Please outline what steps have been taken to ensure that offences relating to counterfeit medical products, as defined in Articles 4.a and 4.j, are criminalised in accordance with Articles 5 and 6. Article 185 of the Criminal Code Counterfeiting of Medicines or Medical Products Article 185 of the Criminal Code (1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years. (2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia. (3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years. (4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices.

	d. Please outline what steps have been taken to ensure that intentional offences described in Article 8 relating to medical products, as defined in Article 4.a, are criminalised. See answer C) e. Please outline what steps have been taken to ensure that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products. Article 185 of the Criminal Code Counterfeiting of Medicines or Medical Products Article 185 of the Criminal Code (1) Whoever manufactures a counterfeit medicinal product, active substance, excipient, medical devices, its components or paraphernalia, or modifies a genuine medicinal product, active substance, excipient or medical device, its components or paraphernalia shall be punished by imprisonment for from six months to five years. (2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified medicinal product, active substance, excipient, medical device, its components or paraphernalia. (3) Whoever counterfeits or modifies the original inner or outer package of a medicinal product or medical device, summary of description of the medicinal product characteristics, the information leaflet, the instructions on use of a medicinal product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years. (4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicinal product or medical device, the summary of description of the medicinal products characteristics, the information leaflet, the instructions on use of a medical devices or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicinal products and medical devices. (5) Whoever commits the offence referred to in paragraph 1, 2, 3 or 4 of this Article by abusing the trust he or she enjoys as an expert, manufacturer or supplier, or commits it through the media suitable for mass distribution, such as information systems, including the internet, shall be punished by imprisonment from one and eight years. (6) The attempt of the criminal offence referred to in paragraph 3 or 4 of this Article shall be punishable. (7) Products and means of production shall be confiscated. f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)? According to the Croatian internal law a legal person may be held liable for an offence established in accordance with Article 11 of the MEDICRIME Convention. In the Republic of Croatia the liability of legal persons for criminal offences is criminal liability. The preconditions of punishability of legal persons are prescribed by the following Articles of the Act on the Responsibility of Legal Persons for Criminal Offences (Official Gazette nos 151/03, 110/07, 45/11, 143/12, hereinafter: the ARLPCO). The Grounds for the Responsibility of Legal Persons Article 3 of the ARLPCO (1) A legal person shall be punished for a criminal offence committed by the responsible person if thereby a duty of that legal person is violated or if the legal person thereby obtained or should have obtained unlawful pecuniary advantage for itself or another.

	(2) Under the conditions referred to in paragraph 1 of this Article, a legal person shall be punished for criminal offences prescribed by the Criminal Code and other laws in which criminal offences are prescribed. The Responsible Person Article 4 of the ARLPCO The responsible person within the meaning of this Act is the natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided Assignment of Guilt of the Responsible Person to the Legal Person Article 5 of the ARLPCO (1) The responsibility of the legal person is based on the guilt of the responsible person. (2) The legal person shall be punished for a criminal offence committed by the responsible person even if the existence is established of legal or material hindrances for establishing the responsibility of the responsible person. The liability of the legal person is without prejudice to the criminal liability of the natural person who have committed the offence, and this is conclusive from Article 5 paragraph 2 of the ARLPCO, as well as from the Article 23 of the ARLPCO, which reads: Joined procedure Article 23 of the ARLPCO (1) For a criminal offence committed by the legal person and the responsible person, joined proceedings shall be conducted and a single judgement shall be passed. (2) If no criminal proceedings may be instituted or conducted against the responsible person for legal or any other reasons whatsoever, the proceedings shall be instituted and conducted against the legal person only. Under the ARLPCO the basis of criminal responsibility of legal person is a criminal offence committed by responsible person of legal person. Responsibility of legal person is based on the guilt of the responsible person (Article 5 of the ARLPCO). Responsible person within the meaning of the ARLPCO is a natural person conducting the affairs of a legal person or a natural person to whom the running of affairs from the legal person's sphere of activity has been confided (Article 4 of the ARLPCO). In accordance with the prescribed legal definition, responsible person is not only a natural person in a leading position who conducts the affairs of legal person (e.g. member of supervisory board), but also a natural person who is under the authority of a person in a leading position, to whom running of affairs from the sphere of activity of legal person has been confided. This is the so-called extended /delegation (derived) model of liability of legal persons in which the liability of a legal person is based on the actions of not only members of the management and supervisory board but also persons ranked lower in the decision-making hierarchy, provided that they are entrusted with conducting the affairs from the scope of operation of legal person. The basis of criminal responsibility of legal person is the fact that a responsible person violated any of the duties of the legal person or the fact that the legal person obtained or should have obtained unlawful pecuniary advantage for itself or third person by criminal offence committed by a responsible person (Article 3 of the ARLPCO). Article 11 paragraph 2 of the MEDICIRME Convention prescribes the criminal liability of legal person where the lack of supervision or control by any natural person, acting either individually or as part of an organ of the legal person, and having a leading position within the legal person, has made possible the commission of an offence established in accordance with the MEDICIRME Convention for the benefit of that legal person by a natural person acting under its authority. Subsequently, based on Article 3 in the acquisition with Article 4 and 5 of the ARLPCO if a natural person under the authority of a natural person in leading position, commits intentionally criminal offence for the benefit of the legal

	person, as a consequence of lack of supervision or control of a natural person in leading position, the liability of legal person will be based on the guilt of a natural person who is not a person in leading position, but has the capacity of responsible person under Article 4 of the ARLPCO and the guilt of the natural person in leading position which had made possible the commission of the criminal offence by the lack of supervision or control. Thus, the model of liability of legal persons for criminal offenses in Croatian legislation, according to which criminal offence may be committed by acting or by omitting to act, is fully in line with the requirements of Article 11 of the MEDICRIME Convention.
France	a. Under French law, the products provided for in Part Five of the Legislative Part of the Code, entitled 'Produits de santé', are considered to be 'health products', mainly: - Pharmaceutical products: o Medicines (art. L. 5111-1), proprietary medicinal products (art. L. 5111-2) and medicinal products of major therapeutic interest (art. L. 5111-4); o Veterinary medicinal products (art. L. 5141-1); o Health products composed of all or part of genetically modified organisms (L. 5150-1); o Health products containing substances in the nanoparticle state (L 5161-1). - Medical devices (art. L. 5211-1) and in vitro medical devices (L. 5221-1). b. In domestic law, the so-called "counterfeit" drug refers to a drug that does not comply with European Union legislation on intellectual and industrial property rights. In the case of medicines, it is most often a trademark or patent infringement. The falsified medicinal product is a medicinal product whose pharmaceutical presentation includes a false presentation (Article L.5111-3 of the Public Health Code): - its identity, including its packaging and labelling, its name or composition, and this on all its components, including excipients, and on the actual dosage of those components, - its source, relating to its manufacturer, its country of manufacture, its country of origin or the holder of its marketing authorisation, - or its history, including records and documents relating to the distribution channels used. Falsified medicines may contain components, including active ingredients, of poor quality or poorly dosed. A drug unintentionally affected by defects or called "non-compliant" refers to a lawful drug with unintentional quality defects due to manufacturing or distribution errors. c-f. Several provisions penalize the counterfeiting of medical products: - Ordinance No 2012-1427 of 19 December 2012 on strengthening the security of the supply chain of medicinal products, regulating the sale of medicinal products on the Internet and combating the falsification of medicinal products provides for criminal penalties relating to the falsification of medicinal products for human use, - Ordinance No. 2013-1183 of 19 December 2013 on the harmonization of criminal and financial sanctions relating to health products and the adaptation of the prerogatives of the authorities and agents responsible for establishing non-compliance, - Law No. 2013-1117 of 6 December 2013 on the fight against tax fraud and serious economic and financial crime, - Law No. 2014-344 of 17 March 2014 on consumption, - Law No. 2014-315 of 11 March 2014 strengthening the fight against counterfeiting, - Law No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry.

	- Ordonnance n° 2018-3 of 3 January 2018 relating to the adaptation of the conditions for the creation, transfer, regrouping and transfer of pharmacies All the conduct covered by the MEDICRIME Convention are thus offences under French criminal law, provided for mainly by the Public Health Code: Manufacture of counterfeit medicines (Article 5): the manufacture of falsified medicinal products for human use is an offence provided for and punished by Article L.5421-13 of the Public Health Code, 5 years' imprisonment and a fine of 375,000 euros The manufacture, distribution, advertising, offer to sell, sell, import and export falsified medicines for veterinary use are offences provided for in Article L.5442-14 of the Public Health Code punishable by a fine of 5 years' imprisonment of 375,000 euros. Supply, offer of supply and trafficking in counterfeits (Article 6): the distribution, the offer to sell, the import, the export of falsified medicines are offences provided for and punished by Article L.5421-13 of the Public Health Code, of 5 years' imprisonment. The possession of falsified medicinal products for human use is an offence punishable by 3 years' imprisonment and a fine of 75,000 euros, which are increased to 5 years' imprisonment and a fine of 375,000 euros if the medicinal product in question is dangerous to health (Article L.5421-14 CSP) Similar offences threatening public health (Article 8): the Public Health Code punishes with 5 years' imprisonment and a fine of 375,000 euros for placing medicinal products on the market without authorisation (Article L.5421-2), or medical devices without certification (Article L.5461-3). In addition, offences provided for in the Criminal Code, the Consumer Code and the Intellectual Property Code make it possible to complete the repressive arsenal applicable in this area: The falsification of documents (Article 7) is an offence provided for in Article 441-1 of the Criminal Code which punishes with 3 years' imprisonment and a fine of 45,000 euros the forgery and use of forgery in any document having as its object or effect the proof of a right or a fact with legal consequences. This text allows, for example, to prosecute the falsification of a medical prescription and its use. Articles L.716-9 and L.716-10 of the Intellectual Property Code punish the acts of counterfeiting of trademarks, designs and models. Article L.615-14 of the Intellectual Property Code punishes patent infringements with 3 years' imprisonment and a fine of 300,000 euros . The Consumer Code, through the offence of deception provided for in Article L.441-1 of the Consumer Code, penalizes the fact of deceiving its co-contractor: 1 ° Either on the nature, the species, the origin, the substantial qualities, the composition or the content in useful principles of all goods; 2 ° Either on the quantity of the goods delivered or on their identity by the delivery of goods other than the specified thing which was the subject of the contract; 3 ° Either on the suitability for use, the risks inherent in the use of the product, the controls carried out, the instructions for use or the precautions to be taken. These acts are punishable by two years' imprisonment and a fine of 300,000 euros (Article L.454-1 of the Consumer Code). These penalties may be

	increased to seven years and a fine of 750,000 euros if the offence or attempted offence has resulted in making the use of the goods dangerous for human or animal health (Article L.454-3). This offence may therefore apply to falsified medicinal products. In addition, Articles L.121-2 et seq. of the Consumer Code penalize misleading commercial practices that consist in creating confusion with another good or service, a trademark, a trade name or another distinctive sign of a competitor. This offence is punishable by two years' imprisonment and a fine of 300,000 euros. In addition, Article 441-2 of the Criminal Code, which punishes with 5 years' imprisonment and a fine of 75,000 euros the forgery and use of forgery in a document issued by a public administration for the purpose of establishing a right, identity or capacity or granting an authorization. In addition, in accordance with article 121-3 of the Criminal Code, which provides that "there is no crime and misdemeanour without intent to commit it", the above-mentioned offences, as well as complicity and attempt in such offences, are intentional. To combat more effectively the counterfeiting of medical products and other similar offences threatening public health, the Ministry of Justice issued a circular of 16 December 2014 presenting the provisions of Ordinance No. 2013-1183 of 19 December 2013 on the harmonization of criminal and financial sanctions relating to health products and the adaptation of the prerogatives of the authorities and agents responsible for recording non-compliance, and texts taken for its application. Finally, on awareness-raising actions, the Ministry of Justice, associated with the Directorate General of Consumption, Competition and Fraud Prevention (DGCCRF), the Ministry of the Interior (police and gendarmerie service), the Ministry of Economy and Finance (customs) and health agencies, published mediguide in December 2011. This tool presented in particular the competent services and the applicable offences in order to facilitate the fight against trafficking in health products and medicines.
Hungary	a. The definition of “medical products” in the Hungarian law complies with the definition of the Convention. The Act C of 2012 on the Criminal Code (hereinafter: CC) establishes two separate criminal offence descriptions regarding the counterfeiting of medicinal products [Section 185/A of CC] and the counterfeiting of medical products [Section 186 of CC]. These two definitions reading together comply with the term of the Convention. Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf 1. However, Section 185/A of CC does not contain a specific definition of “medicinal product”, the content of this term stems from the health law in the following way. • Section 1 point 1 of the Act XCV of 2005 establishes the term of “medicinal product”: it shall mean any substance or combination of substances presented for treating or preventing diseases in human beings or any substance or combination of substances which may be used in, or directly applied to, the human body, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. • Point 3 of the Annex of the Act XLVI of 2008 on food chain and its control determines the definition of “medicines for veterinary use”. It shall mean any substance or combination of substances presented for treating or preventing diseases in animals or any substance or combination of substances which may be used in, or directly applied to, the animal body, either with a view to restoring, correcting or modifying physiological functions

	by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis. Moreover, Section 185/A(8)b) of CC widens the definition and determines that a medicinal product or veterinary medicinal product not licensed in Hungary also means a product where the active medicinal substance is used in violation of the legislative provisions pertaining to the composition of that product. A medicinal product without a marketing authorisation for Hungary shall be considered a licensed medicinal product if it is subjected to an activity specified in section (1) (b) or (d) that may be pursued in a lawful manner after obtaining an authority licence or making a notification as required by law. 2. According to Section 186(5)a) of CC, "medical product" means a medical device, in vitro diagnostic medical device, and investigational medicinal product (test preparation). These terms are also determined by health law. • Section 3 (h) of the Act CLIV of 1997 on health determines the term of "medical devices": any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings or for use on a sample of human origin. • Section 1 point 6 of the Act XCV of 2005 states that "investigational medicinal product" shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products that already have a marketing authorization but are used or assembled (formulated or packaged) in clinical trials in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form of the medicinal product in question. Moreover, Section 186(5)c) of CC widens the definition and determines that medical product not licensed in Hungary also means a medical device placed on the market without conducting a conformity assessment procedure. b. The Hungarian CC punishes – among others – the counterfeiting of medical or medicinal product or the making of counterfeit medical or medicinal product. This distinction exists in the practice as follows: • a counterfeit product gives the appearance of genuine product. In this case a new copy, which is similar to the original product, comes off. The method of the making the counterfeit product or the quality of the result is indifferent. It is not required that the false product seems to be perfect. It has to be only similar to the original product as much as possibility of the deception can be occurred with the using of it; • making a counterfeit product means the modification of an existing genuine product. A new copy does not come off in this case. The perpetrator makes a product, which differs from the genuine product. This term is applicable for both identity and/or source. c. The acts mentioned by Article 5 and 6 of the Convention are included in CC in the criminal offence descriptions. 1. The acts of manufacturing of counterfeits (Article 5 of the Convention) are determined by Section 185/A(1)a) and Section 186(1)a) of CC. According to Section 185/A(1)a) of CC, a person who counterfeits a medicinal product or veterinary medicinal product or makes a counterfeit medicinal product or veterinary medicinal product, is guilty of a felony and shall be punished by imprisonment for up to three years. Pursuant to Section 186(1)a) of CC, a person who counterfeits a medical product or makes a counterfeit medical product, is guilty of a felony and shall be punished by imprisonment for up to three years.

	2. The acts of supplying, offering to supply, and trafficking in counterfeits (Article 6 of the Convention) are determined by Section 185/A(1) b),c) and Section 186(1) b),c) of CC. According to Section 185/A(1) b),c) of CC, a person who • places on the market, trades in, or offers, or hands over unjustified quantities of, a counterfeit or counterfeited medicinal product or veterinary medicinal product, • imports to, exports from, or transports through, the territory of the country, or acquires or keeps an unjustified quantity of, a counterfeit or counterfeited medicinal product or veterinary medicinal product, is guilty of a felony and shall be punished by imprisonment for up to three years. Pursuant to Section 186(1) b),c) of CC • offers, hands over, places on the market, or trades in, a counterfeit or counterfeited medical product, • imports to, exports from, or transports through the territory of the country, or acquires or keeps an unjustified quantity of a counterfeit or counterfeited medical product, is guilty of a felony and shall be punished by imprisonment for up to three years. d. The acts mentioned by Article 8 of the Convention are included in CC in the criminal offence descriptions. I. The acts of the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of • medicinal products without authorisation where such authorisation is required under the domestic law of the Party [Article 8 point a) i) of the Convention]; or • medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party [Article 8 point a) ii) of the Convention] are determined by Section 185/A(1) b),d) and (8)b) of CC and Section 186(1) b),d) and (5)c) of CC. 1. Medicinal products without authorisation where such authorisation is required under the domestic law of the Party [Article 8 point a) i) of the Convention] According to Section 185/A(1) b),d) of CC, a person who • places on the market, trades in, or offers, or hands over unjustified quantities of a medicinal product or veterinary medicinal product not licensed in Hungary, • acquires, keeps, imports to, exports from, or transports through, the territory of the country an unjustified quantity of a medicinal product or veterinary medicinal product not licensed in Hungary, is guilty of a felony and shall be punished by imprisonment for up to three years. According to Section 185/A(8)b) of CC, for the purpose of this section a medicinal product or veterinary medicinal product not licensed in Hungary also means a product where the active medicinal substance is used in violation of the legislative provisions pertaining to the composition of that product. A medicinal product without a marketing authorisation for Hungary shall be considered a licensed medicinal product if it is subjected to an activity specified in paragraph (1) b) or d) that may be pursued in a lawful manner after obtaining an authority licence or making a notification as required by law.

	2. Medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party [Article 8, point a) ii) of the Convention] Pursuant to Section 186(1) b),d) of CC, a person who • offers, hands over, places on the market, or trades in a medical product not licensed in Hungary, • imports to, exports from or transports through the territory of the country, or acquires or keeps an unjustified quantity of a medical product not licensed in Hungary, is guilty of a felony and shall be punished by imprisonment for up to three years. Pursuant to Section 186 (5)c) of CC, for the purposes of this section medical product not licensed in Hungary also means a medical device placed on the market without conducting a conformity assessment procedure. II. The acts of the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party [Article 8, point b) of the Convention] are determined by Section 185/A(1)e) of CC and Section 186(1)e) of CC. According to Section 185/A(1)e) of CC, a person who uses an original document pertaining to a medicinal product or veterinary medicinal product outside its intended use, for a commercial purpose, is guilty of a felony and shall be punished by imprisonment for up to three years. Pursuant to Section 186 (5)e) of CC, a person who uses an original document pertaining to a medical product outside its intended use, for a commercial purpose, is guilty of a felony and shall be punished by imprisonment for up to three years. e. The CC punishes the use of false or falsified public or private deeds (Section 342(1) and 345 of CC). Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf It has to be noted that Hungary took the following declaration concerning Article 7: "Hungary reserves the right not to apply Article 7 paragraph (1) of the Convention on the basis of Article 7 paragraph (2) of the Convention." f. The Act CIV of 2001 on the criminal measures applicable against legal persons sets out the rules of the criminal liability of legal persons
Morocco	1. - Several remarks have been made in this context concerning the criminalization, investigations and prosecutions, but to clarify all this and to be able to understand the Moroccan legislation, it is necessary to read the answers in light of the attributions that were provided to the Profile Questionnaire and additionally: ~~e~~ 2. - The concept of "medical products" in Moroccan law fully corresponds to the definition in Article 4.a: 3. - "For the purposes of this law, "medicinal product" means any substance or combination of substances presented as having curative or preventive properties with regard to human or animal diseases, as well as any product which may be administered to man or animal for the purpose of making a medical diagnosis or restoring, correcting or modifying their organic functions' (Article 1, Law 17.04) . 4. - Medical device: any instrument, apparatus, equipment, material, product, or other article used alone or in combination, including accessories and software involved in its operation, intended by the manufacturer for use in humans for medical or surgical purposes and the principal action of which intended by that medical device is not obtained by pharmacological or

	immunological means or by metabolism, but whose function can be assisted by such means; (Article 1, Law 84.12) 5. - Does the concept of "infringement" in domestic law fully correspond to the definition in Article 4(j) - Any infringement of the rights of the owner of a patent, a certificate of addition, a certificate of layout-design (topography) of integrated circuits, a certificate of registration of an industrial design or a certificate of registration of a trademark or service mark as defined respectively in Articles 53, 54, 99, 123, 124, 154 and 155 above constitutes an infringement (Article 201, Law 17-97). - Penal code: - Harm to the health of others: Article 413. - Law 17-04 on the Medicines and Pharmacy Code: - Illegal practice of pharmacy - Marketing of medicinal products without a marketing authorisation - Opening a pharmaceutical establishment or making extensions or modifications without having declared them to the administration - Pharmaceutical peddling, in any form whatsoever, is strictly prohibited. - Advertising of an unauthorised medicinal product - Law 13.83 on the suppression of fraud, Articles 1, 2 and 5: - offer for sale, sale of falsified medicines dangerous to health. - Law n° 31-08 enacting consumer protection measures, article 3 (Any supplier must, by any appropriate means, inform the consumer of the essential characteristics of the product, good or service, as well as the origin of the product or good and the expiration date). - Dahir 1922 on the Regulation on the Importation, Trade, Possession and Use of Poisonous Substances as amended and supplemented: Traffic in Poisonous Substances - The importation of goods bearing a counterfeit trade mark or service mark within the meaning of Law 17-97 on the protection of industrial property is recorded in the Customs and Indirect Taxes Code as a first-class customs offence provided for in Article 285 and punishable under Article 284. - Law 17-04 on the Medicines and Pharmacy Code (art 132 to 157) - To remember: - Any person who, without a diploma or title, performs any pharmaceutical act as defined by the provisions of this law shall be punished by a prison sentence of 3 months to 5 years and/or a fine of 5000 to 50000 dirhams. - The person responsible for the opening or reopening of a pharmaceutical establishment or for operating it without authorization shall be liable to a fine of 100,000 to 1,000,000 dirhams with closure of the premises operated - The same fine for persons who engage in the sale or distribution of medicines unfit for consumption (without prejudice to the penalties of the Criminal Code) - Law 84-12 on medical devices Article 44: - To remember: - Any establishment that manufactures, imports, exports, distributes or maintains medical devices classified in classes I and II A referred to in Article 4 above shall be punished by a fine of 5 to 7% of the turnover before tax achieved in Morocco during the last financial year closed, but not less than 700,000 dirhams. ~~Who~~ when it: - has placed a medical device on the market without prior registration... - Any establishment engaged in the manufacture, import, export, distribution or maintenance of medical devices classified in classes II, B and III referred to in Article 4 above, shall be punished by a fine of 7 to 10% of the turnover before tax achieved in Morocco during the last financial year closed,

	but not less than 1,000,000 dirhams, ~~who~~ when it commits one of the offences provided for in the first paragraph above. - When it is established that the users of these devices are exposed to the risk of death, the culprit is definitively banned from exercising his activity. - "Anyone who forges, falsifies or alters permits, certificates, booklets, cards, bulletins, receipts, passports, mission orders, waybills, laissez-passer or other documents issued by the public authorities for the purpose of establishing a right, identity or capacity, or granting an authorization, shall be punished by imprisonment for six years months to three years and a fine of 200 to 1,500 dirhams. - The same penalties are applied: - To anyone who knowingly makes use of said forged, falsified or altered documents. (Article 360, Criminal Code)
Russian Federation	The concepts of “medical products” and “falsification” fully comply with the definitions of the Convention (see the responses to the General Overview Questionnaire). In accordance with part 37 of article 4 of the Federal Law of April 12, 2010 № 61-FZ "On the Circulation of Medicines", a falsified medicine is a medicine accompanied by false information about its composition and / or manufacturer. In accordance with Part 12 of Article 38 of Federal Law № 323-FZ "On the Fundamentals of Health Protection of People in the Russian Federation", a falsified medical device is a medical device accompanied by false information about its characteristics and (or) the manufacturer. The Criminal Code of the Russian Federation (hereinafter referred to as the Criminal Code) contains norms aimed at protecting people from criminal offences related to falsification of medical products, as well as illegal circulation and forgery of documents. In particular, Article 235.1 (Illegal production of medicines and medical devices) of the Criminal Code establishes responsibility for the production of medicines or medical devices without a special permit (license), if such a permit (such license) is mandatory (mandatory). In accordance with article 238.1 (Circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements) of the Criminal Code the production, sale or import into the territory of the Russian Federation of falsified medicines or medical devices, or the sale or import into the territory of the Russian Federation of substandard medicines or medical devices, or illegal production, sale or import into the territory of the Russian Federation for the purpose of marketing unauthorized medicines or medical devices, or the production, sale or import into the territory of the Russian Federation of falsified nutritional supplements containing pharmaceutical substances undeclared during state authorization committed on a large scale. Also, Article 327.2 of the Criminal Code provides for criminal liability for the manufacture for the purpose of use or sale or the use of knowingly forged documents for medicines or medical devices (authorization certificate, certificate or declaration of conformity, instructions for the use of a medicine or regulatory, technical and operational documentation of the manufacturer of a medical device. In a pandemic, on the basis of Federal Law № 95-FZ dated 01.04.2020, Article 238.1 of the Criminal Code of the Russian Federation was supplemented with part 1, which provides for liability for “circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements using the mass media or information and telecommunication networks, including the Internet”. These changes are due to the fact that in the context of the pandemic, online stores have gained increased demand, which can be used by fakers of medicines, offering medicines at a lower price, as well as medicines that are supposedly effective for treating or preventing a new coronavirus infection.

	In addition, in relation to actions on the circulation of falsified, counterfeit, substandard and unauthorized medicines, medical devices, as well as falsified nutritional supplements that do not contain a criminal offense, administrative liability is provided under Article 6.33 of the Code of Administrative Offenses of the Russian Federation. According to the data of the state statistical reporting, in 2020, criminal cases on 7 crimes provided for by Article 235.1 of the Criminal Code of the Russian Federation "Illegal production of medicines and medical devices" were in the proceedings of the investigating authorities. Criminal cases about 4 of them were sent to the court for consideration on the merits (in the first half of 2021 - 2 and 2, respectively). There were also criminal cases on 185 criminal acts provided for in 238.1 of the Criminal Code of the Russian Federation "Circulation of falsified, substandard and unauthorized medicines, medical devices and circulation of falsified nutritional supplements." Criminal cases about 26 of them were sent to court (in the first half of 2021 - 64 and 53, respectively).
Spain	a. Article 4 (a) of the Convention provides that 'medical product' means medicinal products and medical devices. The reform of the Criminal Code in 2015 was intended, inter alia, to comply with Article 5 (1) of the Council of Europe Convention on the counterfeiting of medical products and related crimes. Article 5.1 provides for the obligation of States Parties to adopt the necessary legislative measures to criminalise the intentional manufacture of medical products, active substances, excipients, falsified elements, materials and accessories, as well as adulteration of medicinal products, medical devices, active substances and excipients (Article 5.2), supply, supply or trafficking (Article 6.1) and falsification of documents (Article 7.1). The 2015 reform of the Criminal Code introduced a number of new developments affecting the definition of the conduct itself and the material object of crime, which now extended to medical devices such as implants and prostheses. The previous wording of Article 361 referred only to medicinal products as the sole material object. Therefore, the inclusion stems from the ratification of the MEDICRIME Convention and the concept of "medical products" in our national law corresponds to that of the Convention. b. The current Article 362 of the Criminal Code following the reform introduced by Organic Law 1/2015 of 30 March provides that: 'shall be punished with imprisonment of six months to four years, a fine of six to eighteen months and a special disqualification from one to three years, any person who draws up or produces; (a) a medicinal product, including a medicinal product for human and veterinary use, and investigational medicinal products; Or an active substance or an excipient of that medicinal product; (b) a medical device, as well as accessories, components or materials which are essential for its integrity; In such a way as to misrepresent: Their identity, including, where appropriate, the packaging and labelling, the use-by date, the name or composition of any of their components, or, where appropriate, their strength; Its origin, including the manufacturer, the country of manufacture, the country of origin and the holder of the marketing authorisation or documents of conformity; Data relating to compliance with legal requirements or requirements, licences, documents of conformity or authorisations; Or their history, including records and documents relating to the distribution channels used, provided that they are intended for public consumption or use by third parties, and create a risk to human life or health.' The second paragraph states that: 'The same penalties shall be imposed on anyone who alters, in the manufacture or manufacture of the product or at a later stage, the quantity, dose, use-by date or genuine composition, as authorised or declared, of any

	of the medicinal products, substances, excipients, medical devices, accessories, components or materials referred to in the preceding paragraph in such a way as to reduce their safety, efficacy or quality by creating a risk to human life or health'. Prior to the 2015 reform, the verbs used to describe the crime were imitate and simulate medicines, giving them the appearance of real drugs. At present, with the reform of 2015, the conduct is in line with the parameters laid down in the Medicrime Convention. c. New criminal offences and penalties have been introduced in public health offences (Articles 361 to 362c of the Criminal Code) in order to comply with Articles 5 to 8 of the MEDICRIME Convention. Article 361 CC punishes conduct relating to illegal sale of medicinal products; Article 362 CP criminalises the simulation and alteration of medicinal products or medical devices; Article 362a CC punishes conduct relating to trafficking in or the placing on the market of falsified medicinal products or medical devices and Article 362b CC punishes documentary falsifications. The material object of the crime has been extended to include medicinal products for human and veterinary use, active substances and excipients, investigational medicinal products, medical devices, their accessories, elements or materials essential to their integrity. Terminology and definitions have also been adapted to the requirements of the Convention. Article 4 of the MEDICRIME Convention. d. Article 361 of the Criminal Code punishes the production, placing on the market and disposal of illegal medicinal products and medical devices, punishing all stages of the cycle or chain of distribution of medicinal products and medical devices, including the deposit or storage for any of those purposes, where the required authorisation is not available or the necessary documentation is not available, or the elements are in poor condition, either because they have expired, because they have been altered or deteriorated. Article 361 of the Criminal Code is an intentional offence of abstract danger which requires that human life or health be endangered. e.Article 362b of the Criminal Code punishes the conduct of forgery of documents relating to the various documentary elements of medicinal products or medical devices simulated or imitated, the production of which is an offence under Article 362.1 CC. f. Article 11 of the MEDICRIME Convention lays down the obligation for States Parties to take the necessary legislative measures to enable legal entities to be held liable for offences under the Convention committed on their behalf by a natural person acting on their behalf or for having failed to fulfil the duty of supervision or control over natural persons acting under its authority, in terms similar to those of Article 31a (1) of the Criminal Code. Organic Law 1/2015 of 30 March 2007 completely reformed the wording of Article 366 CC, extending to pharmacological offences the criminal liability of legal entities in accordance with the provisions of the Convention.
Switzerland	a. Article 2, para. 1, letter (a) TPA contains a definition of the term 'medical product' which fully corresponds with Article 4.a of the Convention. b. To what extent does the notion of 'counterfeiting' in internal law fully correspond with the definition by Article 4.j as regards medical products? What steps have been taken to ensure that this has been or will be achieved? b.There is no legal definition of the terms 'counterfeiting' or 'counterfeit' in the TPA. However, it can be derived from Article 86, para. 1, letter (g) that the understanding of these terms under the TPA corresponds to that set out in Art. 4.j of the Convention. Pursuant to Article 86, para. 1, letter (g) TPA, any person is punishable by law, if he/she "unlawfully copies, falsifies or

	incorrectly names medicinal products or medical devices [i.e. medical products], or places on the market, uses, imports or exports, or trades in a foreign country, unlawfully copied, falsified or incorrectly named medicinal products or medical devices". Therefore, there was/is no need to supplement the TPA accordingly. c. Please outline what steps have been taken to ensure that offences relating to counterfeit medical products, as defined in Articles 4.a and 4.j, are criminalised in accordance with Articles 5 and 6. c.Cf. the answer given above (Article 86, para. 1, letter (g) TPA). d. Please outline what steps have been taken to ensure that intentional offences described in Article 8 relating to medical products, as defined in Article 4.a, are criminalised. d.Article 8 of the Convention concerns criminal offences in the form of intentional violations of national authorisation and compliance systems that endanger public health without referring to counterfeiting. Given that Article 8 does not require the parties to change their systems of approval and compliance and that it does not contain any additional element compared to Swiss law, the latter did not require any adaptation. The activities mentioned in Article 8 were illegal under Swiss law before the adoption of the Convention, cf. Article 86, para. 1, letter (a) and (d) TPA (formerly Article 86, para. 1, letter (b) and (e) TPA). e. Please outline what steps have been taken to ensure that intentional offences described in Article 7 relating to documents, as defined in Article 4.h, are criminalised when performed in relation to medical products. e.The falsification of attestations or certificates issued by an authority or a conformity assessment body is covered by Article 28 TBTA, to which Article 88 TPA refers. Pursuant to the TPA, the manufacture of therapeutic products is not limited to the production and composition of the chemical, biological, mechanical or electronic components serving as a basis, but also includes packaging, cf. Article 4, para. 1, letter (c). Therefore, counterfeiting of packaging, markings or package leaflets is punishable as unlawful manufacturing (Article 86, para. 1, letter (g) TPA). f. What steps have been taken to proactively bring to the attention of manufacturers and suppliers of medical products the consequences of actions/inactions by legal persons in relation to their business activities relating to medical products (Art. 11)? f.In administrative procedures in case of illegal manufacture and/or supply of medical products, it is regularly underlined that in the case of a further breach of the TPA, a penal procedure will follow. Moreover, Swissmedic mentions in media releases, in regular newsletters to media professionals (listing penalties which entered into force) and in specific answers to the media that infringements of the TPA may be punishable.

Table F-2 - Framework for investigation and prosecution (Q.28)

Belgium	a. The FAMHP has a Special Investigations Unit which deals with cases concerning falsification of medicines and medical devices. The inspectors of this unit all have a pharmaceutical or scientific degree and when they start in this unit are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and other agencies when necessary, which is evaluated case by case) goes through the Pharma and Food Crime Platform.

	b. There are specialised prosecutors who function on a regional basis.
Bosnia and Herzegovina	The competent prosecutor's office decides which police service will carry out investigative actions in accordance with the competences. Several police services and institutions may be involved in the investigation itself, depending on the indicated need and the complexity of the investigation.
Croatia	a.any national specialised investigation units dedicated to: 1) conducting criminal investigations, and/or In Criminal Police Department of Ministry of Internal Affairs there are specialised units like Organised Crime Department, Cyber Crime Department of Ministry of Internal Affairs, International Police Co-operation Department that are dedicated for investigation in the field of falsified medical products. : 2) coordinating and/or supervising criminal investigations by other units/authorities (Article 16), including inter-agency formal or informal committee or structure; Lead roles lie within the Ministry of Internal Affairs or Customs Administration of the Ministry of Finance. Both the Ministry of Internal Affairs and Customs act as enforcement bodies, whilst HALMED gives support in gathering information on counterfeits, cooperates in analysis and quality control of suspected products and shares information on medical products. b.any specialised prosecutors and whether they function on a national or local basis. There are no specialized prosecutors and they function on a national and on a local basis
France	The Ministry of Justice issued a circular of 16 December 2014 presenting the provisions of Ordinance No. 2013-1183 of 19 December 2013 on the harmonization of criminal and financial sanctions relating to health products and the adaptation of the prerogatives of the authorities and agents responsible for establishing non-compliance, and the texts adopted for its application. Some services are more specifically responsible for the investigation and detection of offences in these offences: inspectors from the National Agency for the Safety of Medicines and Health Products (ANSM) and regional health agencies (ARS) the Financial Judicial Investigation Service (SEJF); departmental and regional services and IRGs in cases of acts committed in an organized gang in particular; the Central Office for the Fight against Environmental Damage and Public Health (OCLAESP) with regard more specifically to counterfeits and falsifications relating to health products. Consumer, Competition and Fraud Prevention Officers (CCRF) responsible for investigating and recording violations of laws and regulations relating to certain health products (excluding medicines) OCLAESP and the Service d'enquêtes judiciaires des finances (SEJF), services with national competence, are specialised services capable of dealing with cases involving counterfeit medicines and similar offences within the meaning of Article 16 of the Convention. OCLAESPanime and coordinates the investigations carried out in the fields of the environment and public health, and therefore that related to the counterfeiting of medical products and similar offences. It assists investigators and officials of other interested administrations in the conduct of their investigations. Its role is also to observe, analyze phenomena and centralize information. It is also involved in awareness-raising and training actions. At the international level and in its field of competence, OCLAESP is positioned as a French referent for foreign law enforcement institutions and services. It is the extension of the National Central Bureau France (Interpol)

	for its field of competence and correspondent of Europol and Eurojust. He is also a member of various networks and working groups. As such, OCLAESP has an Investigations Division bringing together the staff in charge of the animation, coordination and conduct of judicial investigations. It also has a Strategy and Analysis Division whose mission is to collect and analyze operational and strategic intelligence for the detection and analysis of emerging transnational phenomena, the coordination of regional actions, and international implementation in environmental and public health matters. It advises the forces of the Ministry of the Interior as well as certain services of partner ministries. Finally, it leads training actions and institutional relations with foreign actors. Within it, the "Groupe Animation Prospective", a single point of entry, receives all requests from OCLAESP, provides support to territorial units in a graduated response format (telephone and documentary support, technical support and operational reinforcement), maintains an expanded and multidisciplinary network of private and public partners, ensures legal monitoring and raises awareness among all stakeholders of public health problems and of the environment in particular emerging phenomena. Last but not least, this group is responsible for evaluating the files in order to provide the most appropriate response to problems as diverse as they are complex. In addition, the "Groupe Appui Intelligence" collects and exploits criminal intelligence, in particular through investigators specializing in open source research. This group also deals with the management of human sources of intelligence and the implementation of special investigative techniques. In addition, for the sake of the effectiveness of the sanction, conduct punished in terms of health protection and constituting administrative failures may be punished by financial sanctions that may be pronounced according to their fields of intervention by the National Agency for the Safety of Medicines or the Regional Health Agencies. Articles L. 5438-1 and L. 5438-2 also provide for the administrative penalties applicable in the event of non-compliance with good manufacturing and distribution practices for pharmaceutical raw materials, or for failing to ensure the conformity of the active substances used for this manufacture. With regard to the falsification of medicinal products and health products, the complexity of the cases, the technical nature of the matter, the extent of the damage, the level of liability in question and the specificity of the products concerned may generally lead to referral to public health centres (Paris or Marseille) on the basis of Article 706-2 of the Code of Criminal Procedure. Indeed, the public health poles (PSP) have a jurisdiction competing with that of all metropolitan and overseas jurisdictions and are in particular competent in matters of health products. They participate in the effective treatment of procedures related to the falsification of particularly complex medicines. Thus, in order to promote the exchange of information and facilitate divestiture, the circular of the Directorate of Criminal Affairs and Pardons of 10 June 2015 specifies the modalities of these exchanges by recommending systematic information to the specialized courts by the local prosecutor's office seized of a procedure that may fall within the criteria defined in Article 706-2 of the Code of Criminal Procedure.
Hungary	a. There is no specialized/designated unit in this area at the police, the investigations are carried out by each police criminal services. Every county police criminal service is involved in this issue. There is a nominee at Criminal Investigation Department of National Police Headquarters (hereinafter: DGCI) at Directorate General for Criminal Investigation, who is responsible for the training of the other police forces and ensures the coordination between territorial police body and the designated unit of Europol. The investigation of Section 185/A and Section 186 of CC is the responsibility of the local police departments, unless the offences cause permanent disability, serious degradation of health or death, or are committed in a criminal conspiracy, and in the case of counterfeiting of medical products, if

	a counterfeit or counterfeited medical product or a medical product not licensed in Hungary becomes widely available to users. In such cases, the county (capital) police headquarters are entitled to conduct the investigation. In special cases, the Airport Police Directorate also acts in these cases. [25/2013 (VI. 24.) BM Decree of the Ministry of Interior on the powers and territorial jurisdiction of the investigative authorities of the Police, 67/2007. (XII. 28.) IRM Decree of the Ministry of Justice and Law Enforcement on determining the territorial jurisdiction of the Police bodies, 329/2007 (XII. 13.) Korm. Decree of the Government on the bodies of the Police and the duties and powers of the Police bodies]. Investigations on counterfeiting of medical and medicinal products are supervised by the district prosecution offices. [Instruction 21/2011 (XII.20.) LÜ of the Prosecutor General on the territorial jurisdiction of prosecution offices] b. In general, the CCP determines the competences between police and the National Tax and Customs Administration (Section 34 of CCP). The decree of the Ministry of the Interior No 25/2013 states which police investigative body (regional or local police department) is responsible for these criminal offences. Under the general rule of jurisdiction, those police department is responsible for these criminal offences on the territory of which the offense was committed.
Morocco	Morocco police force has such units. These are, moreover, those mentioned above, specialised, among other things, in the fight against the offences criminalised by MEDICRIME and similar and related offences. The General Directorate of National Security (Directorate of the Judicial Police) established, at the beginning of the Coronavirus pandemic, a service order whose supervision was entrusted to an ad-hoc command post, to monitor and coordinate, in order to improve the investigation of pandemic-related offences, the action of all operational units and centralize the data they report for analysis and guidance of the responses required according to the evolution of trends. Similar service orders are given to units to combat drug-related crime and their execution is supervised under the same rigorous conditions when participating in dedicated international operations organized by Interpol such as Operation "Pangea".
Russian Federation	b. In accordance with the provisions of Article 151 of the Code of Criminal Procedure of the Russian Federation preliminary investigation in criminal cases of crimes provided for by Articles 235.1, 238.1 and 327.2 of the Criminal Code of the Russian Federation is carried out by investigators of the Investigative Committee of the Russian Federation; crimes provided for by Article 226.1 of the Criminal Code of the Russian Federation - by investigators of the Federal Security Service, investigators of the internal affairs authorities, as well as investigators of the authority that identified these crimes.
Spain	In the field of criminal investigation of matters governed by the MEDICRIME Convention, the Spanish Guardia Civil, the National Police and Customs Surveillance are responsible. The Technical Unit of the Judicial Police of the Spanish Guardia Civil investigates offences related to the material scope of the Convention. Within the National Police, at central level, the specialised section responsible for investigating drug trafficking is the Environment and Doping Consumer Affairs Section of the General Police Station of the Judicial Police. Other decentralised units are also being implemented, which also carry out the same work in the various Jefaturas Superiores o Senior Police Offices. With regard to Customs Surveillance, as part of the judicial police, it is governed in this area by Organic Law on the Repression of Contraband 12/95, considering falsification of medicinal products as prohibited genres or whose possession (among other forms of conduct) constitutes a criminal offence.

	As far as the prosecution Public Prosecutor´s Office is concerned, there is no specialisation in this area, either for investigation or for prosecution. Although there is an interest in creating specialisation, for the time being there is no specialised prosecution office at either national or regional level.
Switzerland	Investigations relating to counterfeit medical products are conducted on a national level by Swissmedic, the FCA and fedpol, whereas on a local level, the cantonal prosecution and police authorities are in charge. According to Article 20, para. 1 ACLA, the staff of Swissmedic and of the FCA who are entrusted with interrogations, inspections and coercive measures must be specially trained. Swissmedic has specific expertise in the field of medical products; should it require specific expertise in IT and financial matters, Article 90c TPA allows for external specialists to be called in as assistants for the safeguarding, evaluation and storage of extensive electronic data stocks. The FCA already has the specialist knowledge required by the Convention in the field of financial investigations and IT, as well as in the securing of assets and electronic data. The cantonal prosecution and police authorities as well as fedpol can rely on their experience in the field of narcotics, since the investigation methods used are similar to those in the medical products sector. The cantonal authorities may also consult the cantonal health authorities, if necessary. Additionally, the Ordinance on the Notification of Cantonal Criminal Decisions requires the cantonal authorities to inform (i.e. supply with a copy) Swissmedic about their criminal decisions based upon the TPA (cf. Article 3 No. 15). Swissmedic for its part has the right to appeal these decisions based on the assessment that the TPA has not been applied correctly (cf. answer 1).

Table F-3 - Lead investigation body; any different arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3.b) (Q.29)

Belgium	a. Depending on the specifics of a case the Prosecutor of the region were the infraction occurs or the FAMPH takes the lead. The Prosecutors have to be notified of all cases even if they do not lead the investigation. The FAMHP has a Special Investigations Unit which deals with cases concerning falsification of medicines and medical devices. The inspectors of this unit all have a pharmaceutical or scientific degree and when they start in this unit are trained to perform investigations. Collaboration with the Federal Police and the Prosecutors (and other agencies, when necessary, which is evaluated case by case) goes through the PFCP. b. In the initial phase of the marketing of the vaccines, an ad hoc consultation platform was set up with the following participants : the FAMHP (SIU), Federal Police and Justice. This was to anticipate possible falsified vaccines and to be able to take coordinated actions as quickly as possible.
Bosnia and Herzegovina	The competent prosecutor's office decides which police service will carry out investigative actions in accordance with the competences. Several police services and institutions may be involved in the investigation itself, depending on the indicated need and the complexity of the investigation.

Croatia	a. the process in place, or planned, for deciding which investigation unit/body takes responsibility/the lead for investigations in general or as they occur; Within the police there are specialised cybercrime units with the extended competence to investigate counterfeit medicine. There is a unit on the national level responsible for the EU and international cooperation and regional units responsible for the cases reported to them or for the cases that occurred within their jurisdiction. Law on Police Affairs and Powers and Rulebook on the manner of conduct of police officers V. CRIMINAL INVESTIGATION Article 38 Criminal investigation begins with the opening of analytical processing or the beginning of the investigation of a criminal offense for which he is prosecuted ex officio or on the basis of a proposal or misdemeanour or by an urgent evidentiary action of a criminal offense or misdemeanour. Criminal investigation generally understands: analytical processing, investigations of a criminal offense or misdemeanour, and final action. The beginning of the investigation of criminal offenses that are prosecuted ex officio and upon the proposal is approved by the competent manager at the proposal of the Task Force and Coordination Group. The criminal investigation is led by a certain police officer. The police officer, on the order of the competent manager, compiles the Criminal Investigation Plan. The criminal investigation plan is approved by the competent manager. Started criminal investigations are entered in the Collection of Criminal Investigations, which is kept on the Information System of the Ministry. The criminal investigation ends: - closing analytical processing; - if the conducted investigations determine that it is not a criminal offense for which he is prosecuted ex officio or a misdemeanour; - by filing a criminal report or a special report against the perpetrator of a criminal offense or by initiating misdemeanour proceedings. Exceptionally, if there is no data necessary for the completion of the criminal investigation at the written proposal of the police officer who conducted the criminal investigation, the superior may grant a temporary suspension of the criminal investigation if all necessary measures and actions have been taken and all available data checked. Reactivation of the criminal investigation referred to in paragraph 7 of this Article in the case of new findings shall be approved by the superior manager at the proposal of the Task Force and Coordination Group. b. if there are any different processes or arrangements in place to coordinate crimes related to a pandemic (Article 16.2, 17.1 and 3. b). there are no different processes related to the pandemic
France	Referral to the relevant investigation service is the responsibility of the territorially competent public prosecutor who directs the criminal investigation and decides on the direction of prosecution. The co-referral of a non-specialized investigation service and OCLAESP ensures in particular a follow-up of the whole of a phenomenon of national scope, such as a pandemic and centralizes the facts followed by the police and gendarmerie services via the central directorates and SIRASCO, carries out reconciliations and supports the investigators. In particular, OCLAESP can provide its expertise if further in-depth investigations are necessary to determine the importance of the phenomenon and allow the identification of more structured criminal teams. In addition, under the third paragraph of Article 28 of the Code of Criminal Procedure, the co-referral now allows police or military officers of the gendarmerie, on the one hand, and agents of public administrations and services to whom special laws assign certain powers of judicial police (for example agents of the CCRF), on the other hand, to contribute to the carrying

	out of the same investigation, with consultation and complementarity of their actions, but under the conditions and within the limits set by the special laws conferring on them powers of judicial police, each thus retaining its own prerogatives. In addition, facts of a high degree of gravity and complexity may justify prompt information by the non-specialised prosecutors' offices of the so-called specialised courts, JIRS and PSP, in their respective fields of competence. Given their expertise in dealing with organized crime and their mastery of international mutual assistance mechanisms, referral to the JIRS is envisaged in cases falling within the criteria of great complexity, in particular when they are committed in several jurisdictions or to the detriment of a multitude of victims. Moreover, as recalled above under Article 706-2 of the Code of Criminal Procedure, the public health units (PSP) are competent for the investigation, prosecution, investigation and trial of offences in the field of public health and the environment under three cumulative conditions relating to the legal classification of the facts, the nature of the product in question and the great complexity of the case. As such, PSPs are competent with regard to offences provided for by the Consumer Code, involving a health product or intended for human or animal food or to which man is permanently exposed and which is regulated because of its effects or dangerousness. In particular, PSPs are intended to deal with technically complex deceptions of national scope in this context, taking into account the extent of the damage caused and the level of liability involved. The international aspect of the case may also constitute a criterion for referral.
Hungary	a.In general, the CCP determines the competences between police and the National Tax and Customs Administration (Section 34 of CCP). The decree of the Ministry of the Interior No 25/2013 states which police investigative body (regional or local police department) is responsible for these criminal offences. Under the general rule of jurisdiction, those police department is responsible for these criminal offences on the territory of which the offense was committed. b.There is no special regulation concerning crimes related to a pandemic.
Russian Federation	The reasons and grounds for initiating criminal cases on crimes of this category are of a general nature and are provided in Article 140 of the Code of Criminal Procedure of the Russian Federation. If there is a need for an expert opinion on the presence/absence of signs of falsification in a particular product, the Ministry of Interior sends a request to Roszdravnadzor to issue a corresponding order to the laboratories subordinate to Roszdravnadzor. The order of work is fixed by the Agreement and the algorithm of interaction between Roszdravnadzor and the Ministry of Interior of Russia on the suppression of the turnover of falsified, substandard and unauthorized medicines and medical devices.
Spain	(a) In the Spanish Guardia Civil there are several channels for entering and exit of events related to this type of crime. A first channel is the Social Security Investigation Group (GISS) of the Criminal Police Technical Unit. The Ministry of Health forwarded to the GISS any reports or suspicions of criminal offences which he is aware of, either directly, from the Autonomous Communities or from the international spheres with which it is linked. The GISS studies, analyses and passes them on the basis of the location of the main event to the various investigation units of the Guardia Civil, which carry out the operational activities necessary for their investigation. Another way of intelligence entry/exit (input/output) to the GISS is through Spanish agencies such as the Spanish Medicines and Health Products Agency (AEMPS), the Spanish Agency for the Protection of Health in Sport (AEPSAD) or the Spanish Food Safety and Nutrition Agency (AESAN), Official Associations and other bodies; At international level, information is shared with EUROPOL, INTERPOL, Police Attachés, other International Agencies and with different countries.

	Another channel would be the Spanish Civil Guard units that are aware, either ex officio or through the various national or international channels, of these crimes. These units would carry out the investigation itself by assuming responsibility for the investigation, or if this is not possible, they would transfer it to another superior or competent unit, but always in the Spanish Guardia Civil. Generally, investigations by the Spanish Guardia Civil are led, at national level, by the central units, and at provincial or Autonomous Community level by the territorial units. (b) In relation to the coordination of investigations between different police forces, all operations, including those related to pandemic offences, are recorded in the Spanish Guardia Civil databases, which are crossed through the Intelligence Centre against Terrorism and Organised Crime (CITCO) with the databases of other police or customs forces. If there are overlaps between the entities under investigation, this body informs the units involved so that they can be coordinated. As regards the pandemic, at international level, INTERPOL has included in its operation PANGEA on internet drug trafficking, medicines and COVID-19 related crimes. Similarly, EUROPOL through Operation SHIELD on drug trafficking has included this type of crime. As well as actively participating in PANGEA and SHIELD, when the pandemic began, a Service Order was drawn up to coordinate and enhance the investigation of offences linked to it, among all units. In the area of Customs Surveillance, there are no specialised units and therefore, the operational unit of the region where the infringement is presumed to have committed the infringement is competent. A Security and Safety Area has recently been set up under Customs Surveillance, which would be responsible for these issues, at least at the level of coordinating investigations. At central level, there is a database of smuggling, in which medicines could probably be filtered.
Switzerland	a.Which investigation body takes responsibility for investigations of counterfeit medical products depends on the criminal jurisdiction to prosecute the case. The Swissmedic Penal Division is responsible for prosecuting perpetrators of violations relating to the manufacture, supply (i.e. import and export) and trafficking of counterfeit medical products, whereas violations in connection with the use and dispensing of counterfeit medical products fall under the jurisdiction of the cantonal prosecution authorities. If the import/export of counterfeit medical products also involves a violation of the Customs Act or the Value Added Tax Act, the FCA will prosecute and judge the offences (cf. Article 90, para. 1 TPA). The TPA provides for the possibility of combining the proceedings under either federal or cantonal jurisdiction if both federal and cantonal jurisdiction applies in a criminal matter that falls within the scope of the TPA's application (cf. Article 90, para. 4 TPA). b.There are no different processes or arrangements in place with relation to a pandemic.

Table F-4 - Dedicated facility available for the public to report information to investigating authorities (that does not relate to pharmacovigilance or product quality defect reports) (Q30)

Belgium	
Bosnia and Herzegovina	
Croatia	Based on the legislation provisions, healthcare professionals, marketing authorisation holders and all natural and legal persons involved in manufacturing and distribution of medicinal products and active substances are obliged to inform the Agency for Medicinal Products and Medical Devices

	(HALMED) on any suspicion of a quality defects or a suspicion of a counterfeit medicinal product. Patients/users may also report to the Agency a suspicion of a quality defect or a counterfeit medicinal product. Agency may also receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior. The legislation defines the responsibilities and timelines for handling such reports and information received, as well as the responsibilities of the Agency to exchange the information as defined in the Compilation of Community Procedures on Inspections and Exchange of Information. Agency is responsible for evaluation and processing of each received report/information on suspected quality defect and counterfeited/falsified medicinal product. Records are kept within the Agency's databases and archive. In order to report any suspicion of a quality defect, adverse drug reaction or counterfeit medicinal product, contact numbers and email addresses for Rapid alert system are available on the Agency's website : Telephone: +385 800 48 00 08 (24 hours a day, free of charge, only for rapid alerts that could lead to a recall) Mobile phone: +385 99 264 6417 (24 hours a day, for rapid alerts that could lead to a recall) Telephone: +385 1 4884 100 (switchboard) Telefax: +385 1 4884 120 (for rapid alerts that could lead to a recall) E-mail: neispravnost@halmed.hr (for all quality defects) Email: nuspojave@halmed.hr (for adverse drug reactions) Email: krivotvorine@halmed.hr (for suspicion in a counterfeited/falsified medicinal products) Handling of quality defects, suspicions in counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was found to be in compliant with the defined legal requirements and set procedures. Legislation provisions: Medicinal Products Act (Official Gazette No. 76/13, 90/14 and 100/18) Article 62 (1) The Agency shall suspend the market placement of the medicinal product and request its withdrawal from the market in one of the following cases: - the medicinal product is unacceptably harmful, or - the therapeutic effect of the medicinal product is insufficient, or - the risk-benefit balance is unfavourable, or - the qualitative and/or quantitative composition of the medicinal product is not as declared, or - the quality and composition or the medicinal product and intermediate product have not been subjected to control, or - the medicinal product is not manufactured in accordance with the manufacturing licence, or - the medicinal product is falsified. Article 181 (1) Healthcare professionals who come in contact with a medicinal product or with a user of the medicinal product, as well as legal and natural persons who manufacture or distribute medicinal products, shall inform the Agency in writing of any incompliance in the quality of the medicinal product brought to their attention.

	(2) In the event of suspected falsified medicinal products, the persons from paragraph 1 of this Article shall notify the Agency of their suspicion within 24 hours. (3) The ordinance on the method for monitoring incompliances in the quality of medicinal products and the ordinance on falsified medicinal products shall be issued by the Minister. Ordinance on the Suspension of the Placement on and Withdrawal of Medicinal Products from the Market (Official Gazette No. 122/14): Article 2 1) Health care professionals coming into contact with medicinal products, or patients/users of medicinal products and legal and natural persons producing or performing the trade of medicinal products are obliged, in the cases that could be the reason for the suspension of the placement on and withdrawal of medicinal products from the market from Article 62 of the Medicinal Products Act (hereinafter: the Act), are obliged to notify the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency) thereof in writing. 2) The patient/user of the medicinal product may report a suspicion of an irregularity in the quality of the medicinal product, or suspicion of a counterfeit medicinal product, to the Agency. 3) In addition to persons from paragraphs 1 and 2 of this Article, the Agency may receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior. Article 6 1) The holder of the marketing authorisation for the medicinal product, holder of the authorisation for the parallel import of the medicinal product, manufacturer of the medicinal product, importers and wholesalers included in manufacturing or in performing wholesale trade of medicinal products are obliged to inform the Agency in writing of each observed case from Article 2 of this Ordinance which could result in the suspension of the placement on or withdrawal of the medicinal product from the market, or limitations to the use of the medicinal product that are not listed in the approved summary of product characteristics and the approved package leaflet. 2) In the case of a suspicion of an irregularity in the quality of a medicinal product, the natural and legal persons from paragraph 1 of this Article are obliged to inform the Agency in writing within: – 12 hours of determining the irregularity, if the irregularity corresponds to a Class I irregularity from Article 12 of this Ordinance, – 24 hours of determining the irregularity, if the irregularity corresponds to a Class II irregularity from Article 12 of this Ordinance, or for a suspicion of a counterfeit medicinal product, – 7 days of determining the irregularity, if the irregularity corresponds to a Class III irregularity from Article 12 of this Ordinance. …. Article 8 1) The Agency shall process every received report from Articles 3, 5 and 6 of this Ordinance immediately upon receipt. 2) The Agency shall determine the responsible person for cases that may be reason for the suspension of placement on or withdrawal of a medicinal product from the market and who will be available 24 hours a day. …. Article 13 1) In the case of a received report of a suspicion of a counterfeit medicinal product, the Agency shall request the pharmaceutical inspection conduct sampling of the medicinal product in order to perform special quality tests and if necessary to implement the procedure prescribed by Article 11, paragraph 1, subparagraph 2 and 3 of this Ordinance.

	2) If the suspicion of counterfeiting is confirmed, the Agency shall, via the Notification Centre of the Republic of Croatia, inform the users of the withdrawal of the medicinal product from the market, while if the legal participant in the marketing of the medicinal product is not determined, the withdrawal procedure shall be carried out by the pharmaceutical inspection. …. Ordinance on the conditions for issuing manufacturing authorisations, on the requirements of good manufacturing practice and on the certificate of good manufacturing practice for medicinal products (Official Gazette No. 83/13 and 32/21): Article 19 … (2) Any complaint concerning a defect shall be recorded and investigated by the manufacturer and the importer of the medicinal product. … Article 20 … (2) The manufacturer or the importer of a medicinal product shall record and investigate any complaint concerning a defect referred to in paragraph 1 of this Article and shall inform the Ministry and the Agency of any defect that could result in a recall or abnormal restriction on use of the medicinal product. … Ordinance on the Requirements and Method of Establishing the Requirements of Good Manufacturing Practice and Good Practice in the Wholesale of Active Substances and on the Procedure of the Entry in the Register of Manufacturers, Importers and Wholesalers of Active Substances, and on Issuing the Certificate for the Implementation of Good Manufacturing Practice (Official Gazette No. 83/13 and 32/21): Article 20 The holder of the entry in the register of manufacturers, importers, or wholesalers shall, immediately and in writing, notify the Agency if he finds out that the active substance received or offered to them is counterfeit or suspected as counterfeit.
France	The National Gendarmerie has set up a number of reporting tools aimed at the public allowing the latter to transmit any kind of information (digital platform, online pre-complaint, social networks ...). These tools are particularly monitored and are subject to regular evaluations.
Hungary	An online reporting platform is available through police.hu, which is anonymous. In addition, police receives notifications from the public by letter and e-mail several times. Police has no information on the effectiveness of these systems. There is a dedicated email address for the purpose to report but information may be sent in any way and all methods are accepted. Mainly the dedicated email address (hamisgyogyszer@ogyei.gov.hu) is used but there is a more confidential facility using electronic forms submitted by the official gateway. Email communication is more effective although less confidential as reports are mostly sent via unprotected email services.
Russian Federation	Citizens can leave an appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact the hotline by phone, or send a complaint through the Unified Portal of Public Services (https://www.gosuslugi.ru /). Such appeals in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ must be considered. Compliance with the requirements of federal legislation is monitored by the Prosecutor General's Office. Citizens' appeals and the timely response to them are recorded and monitored in a special closed subsystem of the Automated Information System of Roszdravnadzor.

	Similar forms of filing appeals are provided in all federal executive authorities (the Ministry of Health of the Russian Federation, the Ministry of Interior, the Prosecutor General's Office, etc.). Information about offenses with the presence of criminal offense signs is transmitted to according investigative or law enforcement agencies.
Spain	
Switzerland	

Table F-5 - Collation of complaints on counterfeit medical products and similar crimes on a national basis for record keeping, analysis, and effective investigation or dealt with on an ad hoc basis by individual investigating authorities/bodies (Q.31)

Belgium	Cases on falsified medical products and similar crimes are collated by the Special Investigations Unit of the FAMHP.
Bosnia and Herzegovina	In addition to the implementation of best practices.
Croatia	Based on the legislation provisions, healthcare professionals, marketing authorisation holders and all natural and legal persons involved in manufacturing and distribution of medicinal products and active substances are obliged to inform the Agency for Medicinal Products and Medical Devices (HALMED) on any suspicion of a quality defects or a suspicion of a counterfeit medicinal product. Patients/users may also report to the Agency a suspicion of a quality defect or a counterfeit medicinal product. Agency may also receive a report or statement of suspicion of a counterfeit medicinal product from the personnel of the Custom's Administration and the Ministry of the Interior. The legislation defines the responsibilities and timelines for handling such reports and information received, as well as the responsibilities of the Agency to exchange the information as defined in the Compilation of Community Procedures on Inspections and Exchange of Information. Agency is responsible for evaluation and processing of each received report/information on suspected quality defect and counterfeited/falsified medicinal product. Records are kept within the Agency's databases and archive. Handling of quality defects, suspicions in counterfeited/falsified medicinal products, adverse reactions and GMP non-compliances is implemented in HALMED's quality system and periodically evaluated through HALMED's internal audits and external audits (e.g. Joint Audit Programme, BEMA). In addition, the key performing indicators (KPIs) are set by HALMED for the mentioned systems and regularly monitored in order to confirm the efficiency of the processes. As per regular assessments performed by HALMED and external audits, the system was found to be in compliant with the defined legal requirements and set procedures. Legislation provisions: Ordinance on the Suspension of the Placement on and Withdrawal of Medicinal Products from the Market (Official Gazette No. 122/14): Article 8 1) The Agency shall process every received report from Articles 3, 5 and 6 of this Ordinance immediately upon receipt. 2) The Agency shall determine the responsible person for cases that may be reason for the suspension of placement on or withdrawal of a medicinal product from the market and who will be available 24 hours a day. …. Please refer to the answer to the Question 30 for more details.
France	According to article 15-3 of the CCP, judicial police officers and agents are obliged to receive complaints filed by victims of breaches of criminal law, including when such complaints are filed in a territorially incompetent judicial police service or unit (...). Any complaint shall be the subject of a report (...).

	The handling of this complaint then depends on the degree of seriousness and the services in charge of the investigation. In the Gendarmerie, there is a principle of subsidiarity in the treatment of criminal proceedings, influencing the unit in charge of the investigation itself, ranging from the territorial service to a specialized judicial police unit with national competence, such as OCLAESP.
Hungary	There is no central body to deal with these complaints. According to Section 376(1)-(2) of CCP, any person may file a crime report regarding a criminal offence subject to public prosecution. Moreover, a member of an authority, a public officer, and, if required by law, a statutory professional body shall file a crime report regarding a criminal offence subject to public prosecution it becomes aware of in its official competence or in his official capacity, respectively. There is a possibility on a case by case basis to investigate on the basis of a complaint, which is investigated by the police or the prosecutor's office supervising each case.
Russian Federation	Acceptance, registration and permission in the territorial bodies of the Ministry of Interior of Russia of statements and reports of crimes is carried out in accordance with the Instruction on the procedure for acceptance, registration and permission in the territorial bodies of the Ministry of Interior of the Russian Federation of statements and reports of crimes, administrative offenses, incidents, approved by the order of the Ministry of Interior of Russia dated August 29, 2014 No. 736. The detailed answer is given in question 23. The interaction of the Ministry of Interior of Russia with Roszdravnadzor is carried out within the framework of the Agreement dated July 31, 2015 No. C2/15/1/6054 "On the procedure for cooperation in terms of countering the turnover of falsified, counterfeit, substandard and unauthorized medicines and medical devices." In accordance with the Federal Law "On the procedure for considering appeals of Citizens of the Russian Federation" dated 02.05.2006 N 59-FZ, citizens, as well as legal entities, can apply to a state authority, and their appeal is obligatory subject for consideration. Citizens can submit an appeal in the appropriate section of the official website of Roszdravnadzor, as well as contact the hotline by phone, or send a complaint through the Unified Portal of Public Services. Such appeals in accordance with the Federal Law "On the procedure for considering appeals of citizens of the Russian Federation" dated 02.05.2006 N 59-FZ must be considered. Compliance with the requirements of this Federal Law is monitored by the Prosecutor's Office. Information about offenses in the presence of signs of a criminal offense is transmitted to investigative or law enforcement authorities. Agreements and algorithms for cooperation and exchange of information in the field of countering the circulation of falsified and counterfeit medicines and medical devices concluded by Roszdravnadzor with the Ministry of Internal Affairs of Russia, the Federal Customs Service of Russia, the Investigative Committee of the Russian Federation provide that information received from citizens can serve as a basis for the start of control and supervisory and investigative measures. Roszdravnadzor publishes information letters for the subjects of circulation about the facts of the identification of falsified, counterfeit, substandard medicines on its official website in the section "Search for medicines withdrawn from circulation". This service provides information about medicines that have been withdrawn from circulation due to non-compliance with their quality. The search parameters are: the trade name of the medicine, the batch number, the name of the manufacturer, the country of manufacture, the status of the medicine, the number of the information letter or the time period: https://roszdravnadzor.gov.ru/services/lssearch.

	Decisions of Roszdravnadzor on medical devices that do not meet the established requirements or are in circulation in violation of the legislation of the Russian Federation are posted on the official website of Roszdravnadzor in the section "Information letters about medical devices": https://roszdravnadzor.gov.ru/services/unreg. In addition, accounting of all cases of falsification of medical products is carried out in the closed part of the Automated Information System of Roszdravnadzor, indicating the full name of the responsible employee of Roszdravnadzor. The official duties of Roszdravnadzor employees involved in the consideration of issues of the circulation of substandard or falsified medical products are fixed in the job descriptions developed within the framework of the Roszdravnadzor quality management system. Also, the QMS of Roszdravnadzor includes SOPs that determine the procedure for reviewing complaints on the issue of falsification, including interaction with other authorities.
Spain	Complaints are not collected at national level in any register. Each Spanish Guardia Civil Unit, when it becomes aware of these crimes, recorded them on the bases of the Corps, where they are available internally for consultation, analysis or investigation, but without being shared with other bodies. Notwithstanding the above, the Guardia Civil in investigations which, because of their importance, novelty or relevance, carry out various intelligence products which they disseminate to their own units and to other bodies or countries. Similarly, in those investigations that require it, intelligence is shared with other countries through channels such as EUROPOL, INTERPOL, police attachés, among others, leading to joint investigations with those countries.
Switzerland	Yes, reports on counterfeit medical products and similar crimes are collated on a national basis. Swissmedic maintains databases of reports regarding counterfeit medical products and similar crimes. Records of investigations and measures are kept. If a local authority is dealing with a case of a crime regarding a medical product in their own jurisdiction, the case will be reported to Swissmedic, too

Table F-6 - Are all prescribed offences in Articles 5-8, and Article 9 investigated? Are they subject to a complaint being made and maintained (Article 15) (Q.32)

Belgium	Yes. They can be investigated without a complaint. If the investigation is the result of a complaint and the complaint is withdrawn the investigation can continue.
Bosnia and Herzegovina	Ongoing with a view to implementing best practices.
Croatia	Yes, all prescribed offences are investigated. Offences established in accordance with this Convention are no subordinate to a complaint and proceedings may continue even if the complaint is withdrawn.
France	Article 1 of the Code of Criminal Procedure provides that public proceedings may be brought by prosecutors or by the injured party. It is apparent from Article 2 of that code that the waiver of civil proceedings may not stop or suspend the exercise of public proceedings. The offences established in articles 5 to 8 and article 9 shall be investigated as soon as their existence is brought to the attention of an investigative service and/or the Public Prosecutor. Investigations and possible prosecutions are not subject to the victim's complaint or maintenance. The initiation of public proceedings falls, for these offences, within the competence of the territorially competent public prosecutor.
Hungary	Yes, all these criminal offences are subject to public prosecution. On the basis of Section 4(1) of CCP, the prosecution service or investigating authority shall

	launch a criminal proceeding ex officio if it becomes aware of a criminal offence subject to public prosecution. Chapter LVIII of CCP sets out the rules of legal remedies available during the investigation. Please see the relevant text.
Russian Federation	Yes. In accordance with paragraph 2 of Article 140 of the Criminal Procedure Code of the Russian Federation, the basis for initiating a criminal case is the availability of sufficient data indicating signs of a crime. The withdrawal of the complaint is not provided for by Russian legislation. Article 76 of the Criminal Code of the Russian Federation allows, by court decision, exemption from criminal liability in connection with reconciliation with the victim for persons who have committed a minor or moderate crime for the first time and have made amends for the harm caused to the victim. The offences provided for by the Convention are classified as moderate or severe, and in practice, the termination of a criminal case in connection with the reconciliation of the parties for the aforementioned offences does not apply.
Spain	The investigation covers all offences referred to in Articles 5 to 8 and Article 9 of the Convention without prior complaint. The investigation is not subject to reporting, as these are crimes which may be prosecuted ex officio. In other words, they are public offences, which may be prosecuted ex officio, in such a way that criminal proceedings for an offence giving rise to ex officio proceedings are not extinguished by the surrender of the offender, in accordance with Article 106 of the Code of Criminal Procedure. In this case, the prosecution will be brought by the Public Prosecutor's Office. Criminal proceedings may be initiated, even without the wishes of the injured party, on the initiative of the Public Prosecutor, which, according to Article 105 of the Code of Criminal Procedure, is obliged to bring criminal proceedings.
Switzerland	Yes, all offences described in the Articles 5-9 of the Convention 9 are investigated. As mentioned above (cf. Question 27 letters (b)-(e) and the answers thereto), the TPA does criminalise the manufacture, supply and trafficking of counterfeits, the falsification of documents and the commission of similar crimes involving threats to public health. With regard to Article 9 of the Convention, the attempt to commit criminal offences under the TPA and "participation in" (aiding or abetting or inciting) such offences are punishable under Swiss law with regard to felonies and misdemeanours pursuant to Articles 22, 24 and 25 of the Swiss Criminal Code (SCC). Art. 86 TPA, by which the Convention has been implemented, specifies misdemeanours in para. 1 and felonies in paras. 2 and 3. The prosecution of these offences does not depend on a complaint as they protect public legal interests ("public health"), whereas under Swiss criminal law, only offences protecting individual legal interests may be subject to a complaint being lodged. Therefore, in the area of crimes involving threats to public health, criminal prosecution is governed by the "formal principle of legality", meaning that law enforcement authorities are obliged to initiate an investigation if they become aware of or receive indications of the existence of such an offence.

Table F-7 - An indicative list of offences, associated with Articles 5-9, 11 and 13 and other criminal laws, to facilitate investigators in deciding the legal basis and the evidence required for successful investigations, in particular during a pandemic when advisory experts and technical staff may not be immediately available (Article 16)? (Q.33)

Belgium	The Law of the 25th of March 1964 on Medicines stipulates all the offences. The inspectors of the Special Investigation Unit of the FAMHP are specialised in this legislation and they assist police and Prosecutors when working in specific cases.
Bosnia and Herzegovina	

Croatia	There is a possibility for competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.
France	See above answer to question 27 (Table F-1)
Hungary	Until now it was not necessary to launch such an indicative list, because advisory experts gave the information for police and National Tax and Customs Administration in time.
Russian Federation	
Spain	
Switzerland	

Table F-8 - The extent of any discretion on whether to initiate and terminate an investigation without reference to a prosecuting authority or other investigating authorities for medical product counterfeiting (Q.34)

Belgium	
Bosnia and Herzegovina	
Croatia	In all cases, according to the Criminal Procedure law, investigating bodies must notify prosecuting authority that criminal investigation has begun. After completing criminal investigation, investigating bodies also have to notify prosecuting authority of the outcome of the criminal investigation.
France	Article 40 of the Code of Criminal Procedure provides that: " The public prosecutor shall receive complaints and denunciations and assess the action to be taken in accordance with the provisions of article 40-1. Any constituted authority, public officer or civil servant who, in the performance of his duties, acquires knowledge of a crime or misdemeanour is required to give notice thereof without delay to the public prosecutor and to transmit to that magistrate all the information, minutes and acts relating thereto. » As highlighted in the circular of 14 May 2004 (Crim- 04-16-E8-14.05.04), the Act of 9 March 2004 enshrines the principle of the expediency of prosecution and establishes the generalization of the criminal response in the event of an offence committed by an identified person. The services and bodies responsible for investigations have the possibility of conducting investigations on their own initiative, but must automatically report to the judicial authority on the outcome of the investigation so that the Public Prosecutor can assess the follow-up to be given to it: initiate proceedings, implement an alternative procedure to prosecution in accordance with the provisions of articles 41-1, 41-1-2 or 41-2 of the Code of Criminal Procedure or dismiss the proceedings if the particular circumstances relating to the commission of the facts justify it (Article 40-1 of the Code of Criminal Procedure).
Hungary	On the basis of Section 4(1) of CCP, the prosecution service or investigating authority shall launch a criminal proceeding ex officio if it becomes aware of a criminal offence subject to public prosecution. Furthermore, a member of an authority, a public officer, and, if required by law, a statutory professional body shall be obliged to file a crime report regarding a criminal offence subject to public prosecution it becomes aware of in its official competence or in his official capacity, respectively [Section 376(2) of CCP]. All grounds for dismissing the crime report (Section 381 of CCP) or for terminating the proceeding (Section 398 CCP) are determined by CCP.
Russian Federation	
Spain	
Switzerland	

Sanctions and aggravating circumstances: identifying what specific legislative and other measures have been taken to support the sanctioning of persons in relation to the counterfeiting of medical products and similar crimes in final sentences, in particular relating offences committed in a pandemic

Table G-1 - internal laws that permit the seizure, confiscation and disposal, including destruction, of medical products, active substances, accessories, parts and materials, and other instrumentalities used to commit the offences described in Articles 5-8 (Article 12. 2. a and b). **(Q35)**

Belgium	Yes. The Law of the 25th of March 1964 on Medicines permits the seizure, confiscation and destruction of falsified medical products, active substances, accessories, parts and materials.
Bosnia and Herzegovina	Noting that the provisions of the Convention have not been implemented in the criminal law of Bosnia and Herzegovina, it should be borne in mind that Article 74 of the Criminal Code of Bosnia and Herzegovina provides as follows: "Paragraph (1) - Cases which in any way have used or were intended to be used for the commission of a criminal offence or which resulted from the commission of a criminal offence shall be confiscated if they are the property of the author. Subsection (2) - The objects referred to in subsection (1) of this article shall be confiscated even if they are not the property of the author, but this does not affect the rights of third parties to be compensated by the authors. Similar provisions are contained in the criminal laws of the entities and the brcko district. In the case of the criminal offences referred to in Articles 212 (Illicit Trafficking) and 213 (Illicit Production), the obligation to confiscate property and objects, i.e. funds intended for the production and processing of goods and objects resulting from such criminal offences.
Croatia	Article 185 of the Criminal Code (7) Products and means of production shall be confiscated. Aiding and abetting the commission of criminal offences established in accordance with the MEDICIRME Convention shall be punished on the basis of general institutes prescribed by Articles 37 and 38 of the Criminal Code. These provisions are located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, they apply to all criminal offences prescribed by the Criminal Code. Confiscation of Objects Article 79 of the Criminal Code (1) The objects and means which are the products of criminal offence shall be confiscated. (2) The court may confiscate objects and means which were intended to be used or were used in the commission of a criminal offence. (3) The court may confiscate objects and means referred to in paragraph 1 and 2 of this Article also in cases where the perpetrator of the unlawful act is not guilty. (4) The confiscated objects and means shall become the property of the Republic of Croatia. This does not affect the rights of third parties to claim damages against the perpetrator for the confiscation of an object or a means. Unless at least his/her gross negligence has contributed to the object or means being intended to be used or being used in the commission of a criminal offence or to its being the product of commission of a criminal offence or if he/she procured the object or means knowing about the conditions allowing for its confiscation, the owner of the confiscated object or means who is not the perpetrator of the offence is entitled to the return of the object or means or to damages equal to its market value paid from the state budget.

	(5) Unless otherwise provided for in a special act, the law may prescribe mandatory confiscation of an object or means, in which case the owner shall not be entitled to damages paid from the state budget. (6) The court may order the destruction of the confiscated object or means. The pecuniary advantage acquired from the commission of the criminal offence referred to in Article 185 of the Criminal Code shall be confiscated on the basis of Article 5 and 77 of the Criminal Code, which apply to all criminal offences prescribed by the Criminal Code. Principle of Confiscation of the Pecuniary advantage Article 5 of the Criminal Code No one shall retain the pecuniary advantage acquired from an unlawful act. Conditions for and Manner of Confiscation of Pecuniary Advantage Article 77 (1) Pecuniary advantage shall be confiscated on the basis of a court decision establishing the commission of an unlawful act. Pecuniary advantage shall also be confiscated from the person to whom it was transferred if it was not acquired in good faith. (2) If the injured party has been awarded a material claim which by its nature and contents corresponds to the acquired pecuniary advantage, the part of pecuniary advantage exceeding the awarded material claim shall be confiscated. (3) The court shall confiscate the pecuniary advantage also in cases where it has instructed the injured party to assert his or her material claim in a civil action. (4) Where it has been established that confiscation in full or in part of objects or rights acquired as pecuniary advantage is impossible, the court shall order the perpetrator to pay the corresponding money equivalent. It may be ordered that payment be made in instalments. (5) The confiscated pecuniary advantage shall not be reduced by the value of resources invested in the criminal activity. (6) The court may decide against the confiscation of pecuniary advantage if its value is negligible. In case the criminal offence referred to in Article 185 of the Criminal Code is committed within the framework of the criminal organization, the Article 78 of the Criminal Code shall also apply. Extended Confiscation of Pecuniary Advantage Article 78 (1) Unless otherwise prescribed by this Article, the provisions of Article 77 of this Code shall apply to the extended confiscation of pecuniary advantage acquired by criminal offence for which the Office for the Suppression of Corruption and Organised Crime is competent and by criminal offences prescribed by Titles XVII. an XXV. of this Code, if pecuniary advantage was acquired by those criminal offences. (2) If the perpetrator of a criminal offence referred to in paragraph 1 of this Article posseses or possesed property that is disproportionate with his or her legitimate income and unless he or she makes it probable that the property is of legitimate origin, it is presumed that such property constitutes a pecuniary advantage. (3) If the pecuniary advantage from a criminal offence have been merged into legitimately acquired property, the entire property shall be subject to confiscation up to the estimated value of the pecuniary advantage. The advantage acquired from property in which the legitimately acquired property was merged with the pecuniary advantage shall also be confiscated in the same manner and in the same ratio. (4) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall be confiscated from a family member irrespective of the legal basis on

	which he or she possesses it and regardless of whether he or she lives in a shared household with the perpetrator. (5) The pecuniary advantage referred to in paragraphs 2 and 3 of this Article shall also be confiscated from another person irrespective of the legal basis on which it was acquired unless this person makes it probable that he or she acquired the advantage in good faith and at a reasonable price. (6) If the person against whom criminal proceedings have been instituted dies, the pecuniary advantage acquired by an unlawful act may be confiscated from his or her successors in proceedings prescribed by a special act.
France	Precautionary measures are possible at the various stages of the investigation, in particular the customs detention of goods (Articles L.335-521-14 and L.716-8 of the CPI), judicial seizures and precautionary measures ordered by the judge of freedoms and detention on referral to the public prosecutor. Law No. 2007-1544 of 29 October 2007 on the fight against counterfeiting also allowed the pre-trial destruction of property seized by decision of the public prosecutor or the judge of freedoms and detention.10, L Article 41-5 paragraph 4 of the Code of Criminal Procedure also authorizes the Public Prosecutor's Office, during the investigation or when no court has been seised or the court seised has exhausted its jurisdiction without having ruled on the fate of the seals, to order the destruction of seized movable property whose preservation was no longer necessary for the manifestation of the truth, in the case of objects qualified by law as dangerous or harmful or whose possession is unlawful. In addition, article 131-21 of the Criminal Code provides that the penalty of confiscation is incurred in the cases provided for by law or regulation and in any case automatically for all crimes and offenses punishable by a prison sentence of more than one year (with the exception of press offenses). It may relate to the object or the direct or indirect proceeds of the offence (article 131-21 paragraph 3), the instrument used to commit the offence or which was intended to commit it, of which the convicted person is the owner or, subject to the rights of the owner in good faith, of which he has the free disposal (article 131-21 paragraph 2) and property of a value correspondent of which the convicted person is the owner or, subject to the rights of the owner in good faith, of which he has the free disposal (article 131-21 paragraph 9). The so-called general/full confiscation penalty also authorizes the confiscation of all or part of the assets belonging to the accused or of which he has the free disposal (Article 131-21 paragraph 6 of the Criminal Code).
Hungary	Yes. According to Section 308 and 324 of CCP, seizure or sequestration shall be ordered during the criminal proceedings. Pursuant to Section 72-76 of CC, confiscation or forfeiture of assets are mandatory to order as a measure. Please see the relevant text. Pursuant to Section 321(3) of the Act CCXL of 2013 on the execution of punishments, measures, certain coercive measures and administrative confinement, the confiscated object shall be destroyed, if the placing on the market – among others - would endanger or violate the public order, public health, environment or public morals. After the material is confiscated by the court, it is then possible to destroy the confiscated material. Destruction takes place in a designated incinerator, in such type of incinerator which has a proper environmental authorization.
Russian Federation	In accordance with Part 19 of Article 38 of Federal Law № 323-FZ, falsified medical devices and substandard medical devices are subject to withdrawal from circulation and destruction on the basis of the decision of the owner of the medical device, the decision of the authorized federal executive authority exercising control and surveillance functions in the field of health safety, or a court decision. The rules for the destruction of seized falsified, substandard and counterfeit medical devices are approved by the Decree of the Government of the Russian Federation of September 15, 2020 № 1440. The decree of the Government of the Russian Federation "On approval of the procedure for the withdrawal from circulation and destruction of falsified

	medical devices, substandard medical devices and counterfeit medical devices", developed by the Ministry of Health of the Russian Federation, is awaiting approval. In accordance with Part 6 of Article 47 of Federal Law № 61-FZ, falsified, substandard medicines are subject to seizure and subsequent destruction or shipment from the Russian Federation, counterfeit medicines - to seizure and subsequent destruction. In accordance with Part 1 of Article 59 of Federal Law № 61-FZ substandard, falsified medicines are subject to withdrawal from circulation and destruction in the order established by the Government of the Russian Federation. The basis for the destruction of medicines are the decision of the owner of the medicines, the decision of the relevant authorized federal executive authority, or a court decision. The rules for the destruction of seized falsified, substandard and counterfeit medicines, were approved by the Government of the Russian Federation dated September 15, 2020 № 1447. In accordance with the first part of Article 81 of the Code of Criminal Procedure, any items are recognized as material evidence: which served as instruments, equipment or other means of committing a crime or retained traces of a crime (paragraph 1); to which the criminal acts were directed (paragraph 2); other objects and documents that can serve as means for detecting a crime and establishing the circumstances of a criminal case (paragraph 3). As a general rule material evidence should be kept in a criminal case until the sentence comes into legal force or until the expiration of the appeal period against a decision or ruling to terminate a criminal case and be transferred along with the criminal case. Within the framework of a criminal case, falsified medical products, active pharmaceutical substances, implements, parts and materials, as well as other means used to commit a crime, may be recognized as material evidence. In accordance with part 3 of Article 81 of the Criminal Procedure Code of the Russian Federation when a verdict is passed as well as a ruling or order to terminate a criminal case the issue of material evidence must be resolved. Wherein: instruments, equipment or other means of committing a crime, belonging to the accused, are subject to confiscation or transfer to the appropriate institutions, or destruction; items prohibited for circulation are subject to transfer to the appropriate institutions or destruction.
Spain	The reform implemented by Organic Law 1/2015 of 30 March 2007 introduced a new Article 362 sexies into the Criminal Code, which provides for the confiscation of substances, objects, products, assets, media, instruments and gains, of all the previous articles of the Chapter, in the following terms: 'In respect of the offences referred to in the preceding articles of this Chapter, the substances, objects and proceeds referred to in Article 359 et seq., as well as property, means, instrumentalities and proceeds, subject to Articles 127 and 128, shall be subject to confiscation.' This reflects the requirements of Article 12 (3) (a) of the Council of Europe Convention on the counterfeiting of medical products and related crimes, which requires signatory States to adopt the necessary legislative measures to allow freezing and confiscation. On the other hand, Article 127 of the Criminal Code lays down the conditions under which confiscation may be ordered, while Article 128 of the Criminal Code deals with cases in which confiscation is not to be ordered, or ordered to a limited extent.
Switzerland	Yes, as the SCC provides for these measures. Pursuant to Article 69, para. 1 SCC, the court shall order the forfeiture of objects that have been used or were intended to be used for the commission of an offence or that have been produced as a result of the commission of an offence in the event that such objects constitute a future danger to public safety, morals or public order. The

	court may (also) order that the objects forfeited be rendered unusable or be destroyed (Article 69, para. 2 SCC). These provisions are applicable regardless of whether the investigation is conducted by Swissmedic or the FCA based on the ACLA (cf. Article 2 which renders applicable the general provisions of the SCC) or by the cantonal prosecution authorities based on the CrimPC.

Table G-2 - Policies facilitating the prosecution of offences in Articles 5-9 along with other criminal law offences arising from the same set of facts on counterfeit medical products, such as intentional offering, for gain, of medical products to prevent or treat the pandemic disease and without the intention to supply such products, also referred to as scamming (Q. 36)

Belgium	
Bosnia and Herzegovina	
Croatia	Counterfeiting of Medicines or Medical Products Article 185 of the Criminal Code (1) Whoever manufactures a counterfeit medical, active substance, excipient, medical product, its components or paraphernalia, or modifies a genuine medicine, active substance, excipient or medical product, its components or paraphernalia shall be punished by imprisonment for from six months to five years. (2) The same punishment as referred to in paragraph 1 of this Article shall be inflicted on whoever procures or offers to supply, stocks, imports or exports, puts into circulation as genuine, counterfeit or modified a medicine, active substance, excipient, medical product, its components or paraphernalia. (3) Whoever counterfeits or modifies the original inner or outer package of a medicine or medical product, summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or documentation on the active substance or excipient shall be punished by imprisonment not exceeding three years. (4) The same punishment as referred to in paragraph 3 of this Article shall be inflicted on whoever uses the original inner or outer package of a medicine or medical product, the summary of description of the medicine characteristics, the medicine information leaflet, the instructions on use of a medical product or the documentation on the active substance or the excipient for purposes other than those for which they were intended for in the legal supply chain of medicines and medical products. (5) Whoever commits the offence referred to in paragraph 1, 2, 3 or 4 of this Article by abusing the trust he or she enjoys as an expert, manufacturer or supplier, or commits it through the media suitable for mass distribution, such as information systems, including the internet, shall be punished by imprisonment from one and eight years. (6) The attempt of the criminal offence referred to in paragraph 3 or 4 of this Article shall be punishable. (7) Products and means of production shall be confiscated. Aiding and abetting the commission of criminal offences established in accordance with the MEDICIRME Convention shall be punished on the basis of general institutes prescribed by Articles 37 and 38 of the Criminal Code. These provisions are located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, they apply to all criminal offences prescribed by the Criminal Code. Solicitation Article 37 of the Criminal Code

	(1) Whoever intentionally incites another to commit a criminal offence shall be punished as if he or she himself or herself has committed it. (2) Whoever intentionally incites another to commit a criminal offence for which an attempt is punishable, but the solicited offence has never even been attempted, shall incur the penalty provided for an attempt to commit such an offence. (3) In the case of an inappropriate attempt of solicitation, the solicitor may receive remittance of punishment. Aiding and Abetting Article 38 of the Criminal Code Punishment may be equal or mitigated to whoever intentionally aids and abets another in the commission of a criminal offence. The attempt to commit criminal offences established in the accordance with the MEDICIRIME Convention shall be punished, as follows: The attempt to commit criminal offences referred to in Article 185 paragraphs 1, 2 and 5 of the Criminal Code is punishable according to Article 34 of the Criminal Code. This provision prescribes the conditions for the attempt to commit a criminal offence to be punishable and it is located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, it applies to all criminal offences prescribed by the Criminal Code. Attempt Article 34 of the Criminal Code (1) Whoever, with the intent to commit a criminal offence, performs an act which is spatially and temporally proximate to the realisation of the material elements of the criminal offence shall be punished for the attempt, provided that a sentence of imprisonment of five years or a more severe punishment may be imposed or that the law expressly provides for the punishment of an attempt. (2) The punishment of a perpetrator of an attempt may be mitigated. (3) If the perpetrator due to gross ignorance attempts to commit a criminal offence by unsuitable means or towards an unsuitable object the court may remit the punishment. The attempt to commit criminal offences referred to in Article 185 paragraphs 3 and 4 of the Criminal Code (for which the maximum sentence prescribed is three years of imprisonment) is punishable on the basis of Article 185 paragraph 6 of the Criminal Code.
France	1/ Manufacture of counterfeit medicines (Article 5): The manufacture of falsified medicines for human use is an offence provided for and punished by Article L.5421-13 of the Public Health Code, 5 years' imprisonment and a fine of 375,000 euros. The manufacture, distribution, advertising, offer to sell, sell, import and export falsified medicines for veterinary use are offences provided for in Article L.5442-14 of the Public Health Code punishable by a fine of 5 years' imprisonment of 375,000 euros. 2/ Supply, offer of supply and trafficking of counterfeits (Article 6): The distribution, offer for sale, import, export of falsified medicines are offences provided for and punishable by Article L.5421-13 of the Public Health Code, 5 years' imprisonment. The possession of falsified medicinal products for human use is an offence punishable by 3 years' imprisonment and a fine of 75,000 euros, which are increased to 5 years' imprisonment and a fine of 375,000 euros if the medicinal product in question is dangerous to health (Article L.5421-14 CSP) 3/ Falsification of documents (Article 7)

	The falsification of documents is an offence provided for in Article 441-1 of the Criminal Code which punishes with 3 years' imprisonment and a fine of 45,000 euros the forgery and the use of forgery in any document having as its object or effect the proof of a right or a fact with legal consequences. This text allows, for example, to prosecute the falsification of a medical prescription and its use. In addition, Article 441-2 of the Criminal Code, which punishes with 5 years' imprisonment and a fine of 75,000 euros the forgery and use of forgery in a document issued by a public administration for the purpose of establishing a right, identity or capacity or granting an authorization. 4/ Similar offences threatening public health (Article 8) The Public Health Code punishes with 5 years' imprisonment and a fine of 375,000 euros for placing medicinal products on the market without authorisation (Article L.5421-2), or medical devices without certification (Article L.5461-3). 5/ Attempt and complicity (Article 9): In accordance with article 121-4 of the Criminal Code, attempted offences are punishable when it is provided for by law. Article L5421-105 of the Public Health Code provides that attempted offences relating to falsified medicinal products for human use is punishable. Pursuant to article 121-7 of the Penal Code: " A person who knowingly, by aid or assistance, facilitated its preparation or consumption is an accomplice to a crime or misdemeanour. An accomplice is also a person who, by gift, promise, threat, order, abuse of authority or power, has provoked an offence or given instructions for the commission of it". 6/ Scam: Article 313-1 of the Penal Code [...] Fraud is the fact, either by the use of a false name or a false quality, or by the abuse of a vraie quality, or by the use of fraudulent manoeuvres, to deceive a natural person or [...] The scam is punishable by five years' imprisonment and a fine of 375,000 euros. [...]
Hungary	It depends on the circumstances of the special case, but these kind of acts are punishable acts on the basis of fraud or other similar criminal offences, such as budget fraud or placing poor-quality products on the market.
Russian Federation	
Spain	
Switzerland	

Table G-3 - policy for offences in Articles 5-9, either generally or during a pandemic, to be subordinate to other criminal law offences in the case of a prosecution of the same person(s), such as the trafficking of controlled substances in the same consignment as the counterfeit medical products (Q. 37)

Belgium	Yes. Because the other offences (i.e. trafficking of controlled substances, criminal organisations) are still more severely punished
Bosnia and Herzegovina	
Croatia	According to Article 51, Paragraph 1 of the Criminal Code, there are no criminal offenses subordinated to other criminal offences (Article 51 paragraph 1: If the perpetrator commits several criminal acts for which he is charged simultaneously, the court will determine his punishment for each criminal act, and then, based on the assessment of the perpetrator's personality and the totality of the committed criminal acts, he will be sentenced to a single punishment).
France	Not
Hungary	Yes, it depends on the circumstances of the special case. Usually concurrence of criminal offences can be determined, e.g. counterfeit medicines and intellectual property offenses.
Russian Federation	
Spain	
Switzerland	

Table G-4 – specific sanctioning policy relating to offences related to counterfeit medical products and similar crimes generally, with specific reference to Article 13 circumstances in so far as they do not already form part of the constituent elements of the offence, and if so, whether the fact that the offence occurred during a pandemic is considered as an aggravating circumstance (Q. 38)

Belgium	Article 16ter of the Law of 25th of March on Medicines lists the aggravating circumstances in which cases the sanctions are doubled : • the offence caused the death of, or damage to the physical or mental health of, the victim; • the offence was committed by persons abusing the confidence placed in them in their capacity as professionals, manufacturers or suppliers; • the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet; • the offence was committed in the framework of a criminal organization; • the perpetrator has previously been convicted of offences of the same nature.
Bosnia and Herzegovina	In the absence of offences specifically provided for in the Convention, it should be noted that Article 48 of the Criminal Code of Bosnia and Herzegovina contains a provision on punishment, which states: "The court shall impose a penalty for the purpose of punishing and taking into account all the circumstances that affect the sentence to be lower or higher (mitigating and aggravating circumstances), and in particular: the degree of guilt, the motives for the crime, the seriousness of the endangerment or harm caused to the protected person, the previous life of the perpetrator, his personal situation and attitude after the commission of the criminal offence, as well as other circumstances related to the person of the perpetrator".

Croatia	Circumstances referred to in Article 13 paragraphs b), c) and d) of the MEDICRIME Convention are constituent elements of the qualified form of the criminal offence Counterfeiting of Medicines or Medical Products referred to in Article 185 paragraph 5 of the Criminal Code. Circumstances referred to in Article 13 paragraphs a), e) and f) of the MEDICRIME Convention may be taken into consideration in the determination of sentence according to Article 47 paragraph 1 of the Criminal Code. This provision is located in the General part of the Criminal Code and, according to Article 6 of the Criminal Code, it applies to all criminal offences prescribed by the Criminal Code. Determination of Punishment Article 47 of the Criminal Code (1) When determining the type and range of punishment, the court shall, starting from the degree of culpability and the purpose of punishment, assess all the circumstances affecting the severity of punishment by type and range (mitigating and aggravating circumstances), and especially the degree of threat to or violation of a legally protected good, motives for having committed the criminal offence, degree to which the perpetrator's duties have been violated, manner of commission and the inculpatory consequences arising from the commission of the criminal offence, perpetrator's prior life, his or her personal and pecuniary circumstances and his or her conduct following the commission of the criminal offence, relationship to the victim and efforts to compensate for the damage.
France	As recalled in question 28, the Ministry of Justice issued a circular of 16 December 2014 presenting the provisions of Ordinance No. 2013-1183 of 19 December 2013 on the harmonization of criminal and financial sanctions relating to health products and the adaptation of the prerogatives of the authorities and agents responsible for noting non-compliance, and texts taken for its application. This circular contains provisions aimed at strengthening the effectiveness of controls and repression in the field of health protection and at better coordinating administrative and criminal sanctions. The aggravating circumstances provided for in Article 13 have been incorporated into our law enforcement system. Indeed, the penalties provided for in Article L.5421-13 of the Public Health Code for the counterfeiting of medicinal products for human use are likely to be aggravated if: - the drug is dangerous for human health; - the acts were committed by authorized pharmaceutical establishments, brokers, indoor pharmacists or community pharmacists, - if the acts were committed in an organized gang. ; - if the offences of advertising, offering for sale or selling falsified medicinal products have been committed on a telecommunications network intended for an unspecified public. The penalties provided for in Article L. 5442-14 of the Public Health Code for the manufacture, distribution, advertising, offer for sale, sale, import and export of falsified medicinal products for veterinary use may be increased to 7 years and a fine of EUR 750 000 where the falsified medicinal product is dangerous for animal or human health or for the environment, when the offences have been committed by authorised pharmaceutical establishments, or by professionals mentioned in Article L5143 -2 or the groups mentioned in Article L.5143-6 of the Public Health Code, when the acts have been committed in an organised group, when the offences of advertising, offering or selling or selling falsified medicinal products have been committed on a telecommunications network for an unspecified public. Furthermore, pursuant to Article 132-10 of the Criminal Code, when a natural person, already definitively convicted of an offence, commits, within five years of the expiry or prescription of the previous penalty, either the same offence or an offence which is assimilated to him under the rules of recidivism, the maximum amount of imprisonment and fines incurred is doubled. Article 132-14 provides for the same increase in penalties for legal persons.

<table>
<tr><td></td><td>Finally, domestic law does not provide for an aggravating circumstance in the event that the offence was committed during a pandemic.</td></tr>
<tr><td>Hungary</td><td>Most aggravating circumstances mentioned in Article 13 of the Convention are parts of the criminal offence descriptions [Section 185/A (3)-(6) and Section 186 § (2)-(4) of CC] as qualified cases, which are punishable with more severe punishment.
However, aggravating circumstances mentioned by Article 13 point e) and f) of the Convention are not part of the criminal offence descriptions. These circumstances are determined in the General Part of CC which have to be applied and taken into account for all criminal offences. It means if the perpetrator committed the criminal offence in a criminal organisation, Section 91 of CC shall be applied automatically. In this case, if a person committed an intentional criminal offence in a criminal organisation, the maximum of the penalty range applicable to the criminal offence shall be doubled, but it shall not exceed twenty-five years.
Or if the perpetrator committed the same criminal offence or similar criminal offences both times, Section 89 of CC shall be applied automatically. According to this rule, regarding a special or multiple recidivist, the maximum of the penalty range of the more recent criminal offence shall be increased by half for imprisonment, but it shall not exceed twenty-five years.
Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf

<table>
<tr><td colspan="2">Article 13 of the Convention</td><td colspan="2">Criminal Code</td></tr>
<tr><td>point a</td><td>death, damage to the physical or mental health</td><td>Section 185/A(3)</td><td>Section 186(2)</td></tr>
<tr><td>point b</td><td>abusing the confidence placed in them in their capacity as professionals</td><td>Section 184/A(5)a)</td><td>Section 186(3)a)</td></tr>
<tr><td>point c</td><td>abusing the confidence placed in them as manufacturers as well as suppliers</td><td>Section 184/A(5)b)</td><td>Section 186(3)b)</td></tr>
<tr><td>point d</td><td>large scale distribution</td><td>Section 184/A(6)</td><td>Section 186(4)</td></tr>
<tr><td>point e</td><td>criminal organisation</td><td colspan="2">Section 91, Section 321</td></tr>
<tr><td>point f</td><td>previous conviction for offences of the same nature</td><td colspan="2">Section 89</td></tr>
</table>

Furthermore, according to the principles of sentencing (Section 80(1) of CC), punishment shall be imposed within the framework laid down in CC, bearing in mind its objective, ensuring that the punishment is appropriate for the material gravity of the criminal offence, the degree of guilt, the degree of danger the perpetrator poses to society, and other mitigating and aggravating circumstances. It means, that the court shall take into account all the time the mitigating and aggravating circumstances.</td></tr>
<tr><td>Russian Federation</td><td>In accordance with paragraph "L" of Part 1 of Article 63 of the Criminal Code of the Russian Federation an aggravating circumstance is the commission of a crime in a state of emergency, natural or other public disaster, as well as during mass riots, in conditions of an armed conflict or in case of war.</td></tr>
<tr><td>Spain</td><td>The 2015 reform of the Criminal Code criminalises the aggravated rates in an autonomous provision. Thus, Article 362 quater of the Criminal Code provides:
‘Penalties higher than those referred to in Articles 361, 362, 362 bis or 362 ter shall be imposed where the offence is committed in one of the following circumstances:
1ª. The guilty person is an authority, a public official, a medical practitioner, a medical practitioner, a teacher, a physical or sporting educator, and obtains himself in the exercise of his or her duties, profession or trade.</td></tr>
</table>

	2ª. That the medicinal products, active substances, excipients, medical devices, accessories, elements or materials referred to in Article 362: (a) have been offered through large-scale means of dissemination; Or (b) were offered or provided to minors, persons with disabilities in need of special protection, or persons who are particularly vulnerable in relation to the product provided. 3ª. The offender belonged to a criminal organisation or group for the purpose of committing such offences. 4ª. The facts were carried out in establishments open to the public by the persons responsible or their employees'. This new regulation, stems from Article 13 of the Council of Europe Convention on the counterfeiting of medical products and related crimes, which requires Parties to take the necessary legislative measures to regard certain cases as aggravating elements of the offences referred to in the Convention, with the exception that these aggravating elements already form part of the very substance of the offence. No specific aggravating circumstance is foreseen in case the crime occurred during a pandemic.
Switzerland	The circumstances referred to in Article 13 of the Convention must be taken into account by the Swiss courts under Article 47 SCC. In the event of circumstances according to Article 13, letter (a) (endangerment of life and health), the penalty under the SCC is determined according to the severity of the violation. The abuse of trust according to Article 13, letters (b) and (c) indicates that the perpetrator acted with special knowledge and volition, which must be taken into account when assessing the penalty under Article 47, para. 2 SCC. The use of opportunities for large-scale distribution (Article 13, letter (d)) speaks in favour of the intention to conduct business on a large scale and thus endanger a large number of people. This is also an element that increases fault under Article 47, para. 2 SCC. The commission of the offence within the framework of a criminal organisation (Article 13, letter (e)), constitutes an offence in itself, which can be taken into account as an aggravating factor when determining the "concurrence of laws" (Article 260ter SCC). Repeated offences (Article 13, letter (f)) have always been taken into account in the assessment of penalties under Swiss law, cf. Article 47, para. 1 SCC. The occurrence of the offence during a pandemic is not generally considered an aggravating circumstance. However, if the perpetrator takes advantage of the pandemic or the offence is connected to the pandemic in other ways (e.g. production of falsified vaccines in large quantities which are then administered to the population), this may have a negative effect on the culpability of the perpetrator which is (also) assessed according to the reprehensibility of his/her conduct (cf. Article 47, para. 2 SCC).

Table G-5 - if and to what extent internal law provides for the possibility of removing the professional status of a person who abused the confidence placed in them in their capacity as a professional (Articles 12.2 and 13. b) or, including legal persons, as manufacturers and suppliers (Article13. c). (Q. 39)

Belgium	For legal persons: the manufacturers and distributors are subject to licensing according to the Law of the 25th of March 1964 on Medicines. The Royal Decree of the 14th of December 2006 (the implementing decree of this law) lists all the obligations of the license holders. If they commit infringements, these licenses can be suspended or revoked. Moreover they can also be prosecuted for these infringements.
Bosnia and Herzegovina	
Croatia	Act on Medicine

	Termination of the right to practice medicine Article 7 The right of a doctor to perform medical activity ceases: 1. if he loses Croatian citizenship, 2. if he loses his legal capacity, 3. if he becomes permanently unhealthy to perform medical activities, 4. if a security measure of prohibition of performance has been imposed on him medical activities, 5. if the disciplinary sanction of the body of the Croatian Medical Chamber lost the right to practice medicine. Unworthiness to perform medical activity Article 8 A doctor who has been found guilty by a final court decision for the commission of a criminal offense may, given the importance of the nature of the endangered good or other consequences and with regard to the circumstances under which the action was performed or missed, considered unfit to practice medicine. The doctor referred to in paragraph 1 of this Article may be denied administration approvals for independent work, ie temporarily or permanently revoked approval for independent work. Depending on the type of crime and the consequence it had, the doctor referred to in paragraph 1 of this Article may be temporary or permanent limited authorization for independent work given the scope and the type of work that the doctor is allowed to do. Unworthiness to perform medical activity is determined by an administrative act, a body determined by the Statute of the Croatian Medical Association chambers Act on Pharmacy Article 29 The Chamber may temporarily or permanently revoke the master's degree in pharmacy from independent work. The approval is temporarily revoked for a period of up to one year, ie for the reasons for which the approval was revoked. Approval shall be suspended: - if the master of pharmacy has not fulfilled the conditions prescribed by the general act of the Chamber of Professional Development for the purpose of maintaining and improving the quality of health care, for the period until he meets the required conditions, - if the Master of Pharmacy is temporarily prohibited from performing pharmacy activity by a decision of the Chamber of the Chamber, a final decision of a regular court or a decision of another body, - if the master of pharmacy in his work acts contrary to the provisions of this Act, for a period until he eliminates such action. Approval is revoked permanently: - if the master of pharmacy is permanently prohibited by the decision of the court of the Chamber, a final court decision or a decision of another body from performing pharmacy activity. Medicinal Products Act Article 80 (1) The Agency shall, ex officio, issue a decision on cancellation of the manufacturing authorisation if it is established that the manufacturer does not comply with the requirements laid down by this Act and the ensuing regulations.

	(2) On the basis of a written application of the authorisation holder the Agency shall by a decision revoke the manufacturing authorisation if the authorisation holder ceases its activity. (3) The decision on revoking or withdrawing of the manufacturing authorisation cannot be appealed, but administrative proceedings can be instituted against it. ORDINANCE ON THE REQUIREMENTS AND METHOD OF ESTABLISHING THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICE AND GOOD PRACTICE IN THE WHOLESALE OF ACTIVE SUBSTANCES AND ON THE PROCEDURE OF THE ENTRY IN THE REGISTER OF MANUFACTURERS, IMPORTERS AND WHOLESALERS OF ACTIVE SUBSTANCES, AND ON ISSUING THE CERTIFICATE FOR THE IMPLEMENTATION OF GOOD MANUFACTURING PRACTICE VIII. DELETION FROM THE REGISTER Article 35 The Agency shall issue a decision on the deletion of manufacturers, importers, or wholesalers of active substances from the Register in the following cases: – at the request of the holder of the entry in the Register, – if the holder of the entry in the Register is not registered in the court register, or crafts register, – if it has been established after an inspectional supervision that the holder of the entry in the Register does not meet the requirements for the implementation of activities of manufacturing active substances pursuant to the Act and this Ordinance.
France	For natural persons, Article 131-6 15° of the Criminal Code provides, as an alternative penalty to imprisonment, for the possibility for the court to pronounce for an offence punishable by imprisonment (including the conduct referred to in the MEDICRIME Convention) and instead of imprisonment, a prohibition, for a period of up to five years, to exercise a commercial or industrial profession, to direct, administer, manage or control in any capacity, directly or indirectly, for his own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Where the law so provides, natural persons may also incur the additional penalty of prohibition, in accordance with the procedures laid down in Article 131-27 of the Criminal Code, either from exercising a public function or from exercising the professional or social activity in the exercise or in connection with the exercise of which the offence was committed, or from exercising a commercial or industrial profession, to direct, administer, manage or control in any capacity, directly or indirectly, for their own account or on behalf of others, a commercial or industrial enterprise or a commercial company. Similarly, legal persons declared criminally liable, under the conditions laid down in Article 121-2 of the Criminal Code and as provided for by law, may also be sentenced to an additional penalty of dissolution and a prohibition mentioned in 2 ° of Article 131-39 of the Criminal Code relating to the activity in the exercise or on the occasion of the exercise of which the offence was committed.
Hungary	As we mentioned above, Article 13 point b) and c) of Convention are considered qualified cases in CC. Moreover, disqualification from a profession (Section 52-53 of CC) is another punishment which can be imposed next to the imprisonment. Please see the relevant text: https://njt.hu/translation/J2012T0100P_20210708_FIN.pdf In connection with legal persons, according to Section 3 of the Act CIV of 2001 on the criminal measures applicable against legal persons if the court imposes punishment on the person committing the criminal offence defined in Article 2 or applies reprimand or probation against this person, orders confiscation or forfeiture of assets, it may apply the following measures against the legal person:

	a) winding-up the legal person, b) limiting the activity of the legal person, c) imposing a fine.
Russian Federation	One of the criminal punishment provided (as an additional one), inter alia for the circulation of falsified, substandard and unauthorized medicines, medical devices and the circulation of falsified nutritional supplements (Article 238.1 of the Criminal Code of the Russian Federation), is deprivation of the right to hold certain positions and be engaged in certain activities, consists in the prohibition to hold positions in the public service, in local self-government authorities, or to be engaged in certain professional or other activities. At the same time, by part 3 of Article 47 of the Criminal Code of the Russian Federation, deprivation of the right to hold certain positions or be engaged in certain activities can also be imposed as an additional type of punishment in cases where it is not provided for by the corresponding article of the Special Part of the Criminal Code of the Russian Federation as a punishment for the corresponding crime, if, taking into account the nature and degree of social danger of the crime committed and the personality of the guilty person, the court finds it impossible to retain his right to occupy certain positions or engage in certain activities.
Spain	
Switzerland	

Data Collection: the effective collection, collation and analysis of data that can support the fight against counterfeit medical products and similar crimes involving threats to public health in a pandemic, and in general.

Table H-1 - whether data is collected for the purpose of observing and evaluating the phenomenon of counterfeit medical products or for another purpose (Article 17.3.a and b). (Q.40)

Belgium	The FAMHP (SIU) collects information on 2 levels: the level of research files and the level of postal items a.The data collection is a standard activity of the service for the purpose of risk management & prioritization of the service b. During the COVID pandemic, the period between different internal analyses was shorter with more regular reports. The focus was on the type of drugs found in postal packages & medical devices because this changed drastically. Therefore, reports with analyses were made specifically about the COVID-related drugs and medical devices c. In collaboration with the Customs Department 'Risk Management' : creation of a list of external characteristics and parameters (shipper, country of shipment, route of shipment, description of contents, value, weight, etc.) of shipments to target suspicious shipments and collect further data. d. This is a very extensive subject and is too extensive to be answered in a single question. e. The reports were shared with Federal Police services, Public Prosecution Service,

	Customs, where useful Europol and other European competent authorities such as the ANSM in France, IGJ in The Netherlands
Bosnia and Herzegovina	
Croatia	Data about tested falsified medical products are stored in database of Agency for medicinal products and medical devices. This data are shared with the OMCL network and with other authorities through Rapid Alert System and the KnowX database. Data about falsified medical products found during police and customs investigation and not tested also are shared through Know X database and Rapid Alert System. Agency for medicinal products and medical devices yearly is obliged to prepare a report on its activities related to falsified medical products for the OMCL network. In the framework of CD-P-PG/CMED working group (EDQM, Council of Europe) there is also a form of exchange of information about falsified medicinal products and medical devices especially during pandemic.
France	
Hungary	a. b. c. There is no special system for collecting data. Police collects every data of criminal case by own system which called RobotZsaru Neo. d. e.
Russian Federation	The procedure for collecting and recording information about the falsification of medical products is described in detail in question 31. As indicated in question 24, during the pandemic, medicines used to treat coronavirus infection were taken under special control. The results of selective control are also recorded in the automated information system of Roszdravnadzor. These databases allow you to filter and search information by date, product name, so a separate analysis of the information obtained during the pandemic, including by individual product names, is possible
Spain	
Switzerland	